

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

WEST BOCA MEDICAL CENTER, INC.,

Plaintiff,
v.

AMERISOURCEBERGEN DRUG CORPORATION;
CARDINAL HEALTH, INC.;
MCKESSON CORPORATION;
PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICAL INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
NORAMCO, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
INSYS THERAPEUTICS, INC.,
ALLERGAN PLC f/k/a ACTAVIS PLS;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;
MALLINCKRODT PLC;
MALLINCKRODT LLC;
CVS HEALTH CORPORATION;
THE KROGER CO.;

COMPLAINT

JURY TRIAL DEMANDED

This Action Relates to:

Case No. 1:17-MD-2804

Hon. Dan A. Polster

Under:

Organized Crime Control Act of 1970, IX, Racketeer Influenced and Corrupt Organizations Act, P.L. No. 91-452, 84 State. 922 (1970), (codified at 18 U.S.C. §§ 1961-1967 (2012) (“RICO”)

Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.

Fraudulent Practices –Misleading Advertising, Fla. Stat. Ann. § 817.41

Breach of Implied Warranty of Fitness for a Particular Purpose, Fla. Stat. Ann. §§ 672.315 and 672.11

Negligence

Wanton Negligence

Negligence Per Se

Negligent Marketing

Negligent Distribution

Nuisance

~~RITE AID OF MARYLAND, INC.;~~
WALGREENS BOOTS ALLIANCE,
INC.; and
WAL-MART, INC.

Defendants.

Unjust Enrichment

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The decade of the 1990s was the era of the blockbuster drug, the billion-dollar pill, and a pharmaceutical sales force arms race was part of the excess of the time . . . A pharmaceutical Wild West emerged. Salespeople stampeded into offices. They made claims that helped sell the drugs to besieged doctors. Those claims also led years later to blockbuster lawsuits and criminal cases against their companies.¹

COMPLAINT

Plaintiff West Boca Medical Center, Inc. brings this Complaint against Defendants AmerisourceBergen Drug Corporation; LLC; Cardinal Health, Inc.; McKesson Corporation; Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Insys Therapeutics, Inc., Allergan plc f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt Plc; Mallinckrodt LLC.; CVS Health Corp.; The Kroger Co., ~~Rite Aid of Maryland, Inc.~~; Walgreens Boots Alliance, Inc.; and Wal-Mart, Inc. (collectively “Defendants”) under the Organized Crime Control Act of 1970, IX, Racketeer Influenced and Corrupt Organizations Act, P.L. No. 91-452, 84 Stat. 922 (1970), (*codified at* 18 U.S.C. §§ 1961-1967 (2012) (“RICO”); Controlled Substances Act of 1970, 84 Stat. 1236, 1242 (*codified at* 29 U.S.C. § 801, et seq.) (2012); Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.); Fraudulent Practices –Misleading Advertising, Fla. Stat. Ann. § 817.41; Breach of Implied Warranty of Fitness for a Particular Purpose, Fla. Stat.

¹ Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* at 133 (Bloomsbury Press 2015) (hereinafter referred to as “Dreamland”).

Ann. §§ 672.315 and 672.11; Negligence; Wanton Negligence; Negligence Per Se; Negligent Marketing; Negligent Distribution; Nuisance; and Unjust Enrichment seeking judgment against Defendants and in favor of Plaintiff; compensatory damages; treble damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief and alleges as follows:

INTRODUCTION

A. The Opioid Crisis

1. Hospitals in South Florida and elsewhere encounter patients with opioid-related conditions daily. On one end, hospitals must deal with patients who have serious medical conditions that require extra care and expense because the patient is opioid addicted, and on the other, hospitals must utilize their resources to handle the “pill seekers.” Take for example this situation: Two very pregnant women present themselves for treatment – a healthy one and an opioid-addicted one. Both are admitted. Regardless of whether either patient can pay, they both must be admitted under prevailing federal and state law for medical and possible psychiatric care, even though the hospital knows it may not be compensated in full, or perhaps at all for its medical services. Both women give birth. The opioid-addicted mother has an opioid-addicted child, who enters this world kicking and screaming as he or she goes through the addiction withdrawal process. That baby is taken to a neonatal intensive care unit, often referred to as the “NICU,” with sophisticated medical equipment, supplies and staff specially trained to treat the needs of opioid-addicted babies. The healthy mother and her child’s stay in the hospital is completed in two or three days and costs a few thousand dollars, which is likely paid by an insurer. The opioid-addicted mother and her addicted baby each require special treatment and attention for opioid withdrawal, which likely is uncompensated or undercompensated even if the mother has insurance. The mother stays as long as is necessary to stabilize her condition, but

because of her opioid addiction her new baby may spend months in the hospital receiving around-the-clock care. Ultimately, the hospital has a duty to treat both new mothers and their babies, yet the cost to the hospital for this duty is much greater for the opioid-addicted mother and baby, which results in higher uncompensated costs to that hospital.

2. These two very different encounters play out daily at West Boca Medical Center, Inc. “[C]ases of drug addicted newborns rose by double digits” in Florida in 2016.² “Among the \$967 million in charges for their care were 97 ‘million-dollar babies’ whose treatment costs topped seven figures each. Eight of the infants were born in Palm Beach County,”³ where Plaintiff West Boca Medical Center is located.

3. Florida hospitals, of course, are not unique in dealing with the opioid epidemic. Hospitals across the United States are the front-line treatment for victims of the opioid epidemic. Hospitals — legally and morally — are compelled to treat patients with opioid-related conditions and, as a result, have been directly damaged by the epidemic. In addition to the cost of the opioid drugs themselves, hospitals have and continue to incur millions of dollars in damages for the costs of uncompensated care as a result of the unlawful marketing, distribution and sale of opioids.

4. The United States is in the midst of an opioid epidemic caused by Defendants’ unlawful marketing, sales, and distribution of prescription opioids that has resulted in addiction,

² Pat Beall and Mike Stucka, *Cost of heroin epidemic tops \$1 billion a year in Florida*, PALM BEACH POST, (Dec. 17, 2016), <https://www.mypalmbeachpost.com/news/cost-heroin-epidemic-tops-billion-year-florida/WYamI7pzwIHmKf3mzY8H/>.

³ *Id.*

criminal activity, serious health issues, and loss of life.⁴ According to the Centers for Disease Control (“CDC”), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.⁵

5. A particular tragedy of the opioid epidemic is that it has turned law-abiding citizens, who experience routine injuries into drug addicts, and in some cases, ruin their lives.

6. Across the nation, hospitals are struggling from the relentless and crushing financial burdens resulting from the epidemic of opioid addiction and abuse. Every day, more than 115 Americans lose their lives after overdosing on opioids.⁶ The effects of the opioid epidemic on hospitals may soon become even worse. The coverage rules under the Affordable Care Act (ACA) are in transition, thus creating the possibility of increased costs for hospitals for treatment of opioid-addicted patients admitted under the Emergency Medical Treatment and Labor Act (“EMTALA”), 42 U.S.C. § 1395dd.⁷

7. According to the CDC, opioid overdoses killed more than 45,000 people in the 12 months that ended in September, 2017. It is already the deadliest drug epidemic in American history.⁸ If trends continue, lost lives from opioid overdoses will soon represent the vast majority

⁴ As used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic, and semi-synthetic opiates.

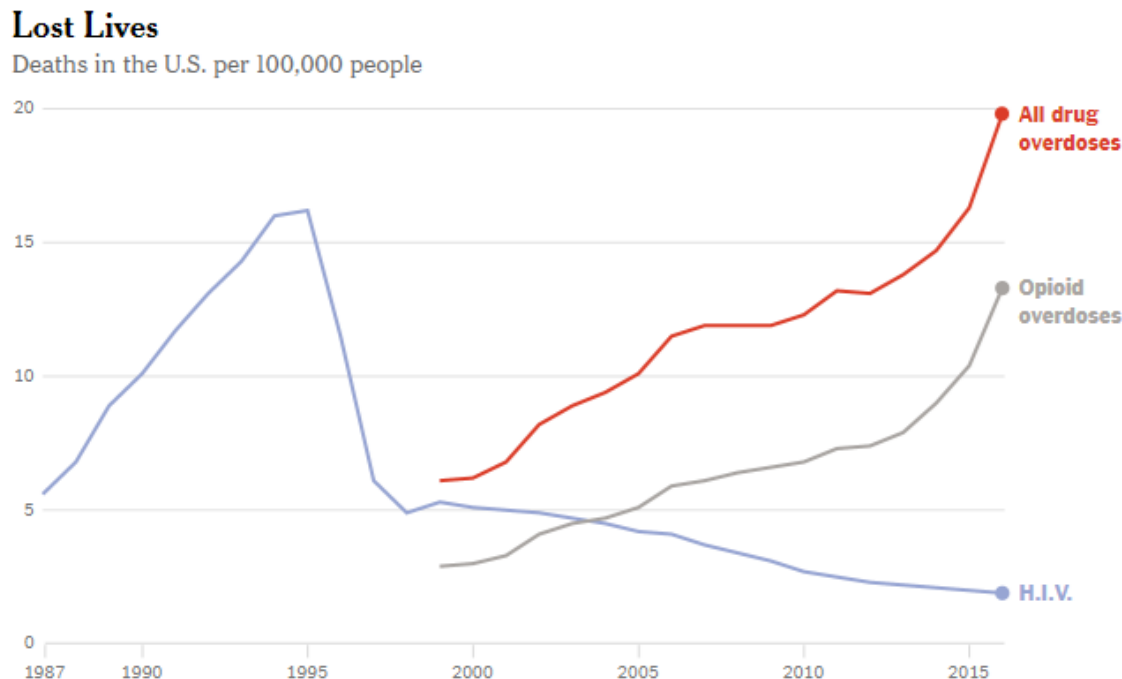
⁵ Centers for Disease Control and Prevention, *Prescribing Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>, (last accessed April 30, 2018).

⁶ Opioid Overdose Crisis, National Institute on Drug Abuse (revised March 2018), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one>. (“Opioid Crisis, NIH”).

⁷ American Hospital Association, *AHA Priorities to Address the Opioid Crisis*, <https://www.aha.org/guidesreports/2018-03-02-aha-priorities-address-opioid-crisis>, (last accessed April 28, 2018).

⁸ The Editorial Board, *An Opioid Crisis Foretold*, (Apr. 21, 2018), <https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html>.

of all drug overdose deaths in the United States.



Note: Drug overdose data available since 1999. Source: Centers for Disease Control and Prevention | By THE NEW YORK TIMES.⁹

8. Between the start of the century and the year 2014, opioid-related death rates increased by 200%. Fourteen percent of that increase occurred between 2013 and 2014.¹⁰

9. The opioid epidemic is killing scores of individuals each day, and having a similarly drastic impact on the total price tag for hospital care.

10. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹¹ In many cases, heroin abuse starts with opioid abuse.

⁹ *Id.*

¹⁰ *Id.*

¹¹ See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016), doi: 10.1056/NEJMSr1601307, <http://www.nejm.org/doi/full/10.1056/NEJMSr1601307>.

11. According to the CDC, the United States is currently seeing the highest overdose death rates ever recorded.¹² As opioid related deaths increase, the life expectancy in the United States has decreased.¹³

12. Perhaps more than any other institution, hospitals directly bear the brunt of the opioid crisis. The state of Florida has been one of the most affected states in the nation. On May 3, 2017, Governor Rick Scott declared the opioid epidemic a public health emergency in Florida citing to statistics from the CDC finding that in 2015, opioids were responsible for over 33,000 deaths nationwide and nearly 3,900 deaths in Florida.¹⁴

13. On October 28, 2017, President Trump did the same, declaring the opioid crisis a public health emergency.¹⁵

14. This suit takes aim at a primary cause of the opioid crisis: A False Narrative marketing scheme in which members of the supply chain joined and conspired in the false and deceptive marketing of prescription opioids, which was designed dramatically to increase the demand for and sale of opioids and opioid prescriptions.

15. On the demand side, the crisis was precipitated by the defendants who

¹² Jessica Glenza, *Opioid crisis: overdoses increased by a third across US in 14 months, says CDC*, THE GUARDIAN (March 6, 2018), <https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc>.

¹³ National Center for Health Statistics, *Life Expectancy*, available at <https://www.cdc.gov/nchs/fastats/life-expectancy.htm>, (last accessed April 30, 2018); Centers for Disease Control and Prevention, *U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids*, (March 18, 2018), <https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html>.

¹⁴ Executive Order 2017-146 (2017). Available at https://www.flgov.com/wp-content/uploads/orders/2017/EO_17-146.pdf. See also, Executive Orders 2017-177 and 2017-230 (2017).

¹⁵ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, The New York Times (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>

manufacture, sell, and market prescription opioid painkillers (“Marketing Defendants”). These opioids have various brand names and generic names, and include “OxyContin,” fentanyl, hydrocodone, oxycodone, and others mentioned in this Complaint. Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

16. The Marketing Defendants’ goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

17. The Supply Chain Defendants —Distributor Defendants and National Retail Pharmacies Defendants—saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities under the Controlled Substance Act, and flooded affected areas with opioids well knowing they were contributing to, but profiting from, widespread addiction and human misery.

18. And succeed they did. Opioid abuse has quickly become one of the nation’s most pressing health management issues, not only because of its toll on patients, but increasingly

because of the financial impact on hospitals and the rest of the healthcare system.¹⁶

19. The Marketing Defendants and Supply Chain Defendants extract billions of dollars of revenue from the addicted American public while tens of millions of dollars of injury are caused to hospitals as the reasonably foreseeable consequences of the prescription opioid addiction epidemic. Indeed, Defendants depended on the hospitals to mitigate the health consequences of their illegal activities – at no cost to the defendants – thereby permitting the defendants to perpetuate their scheme. The defendants knew that but for the hospitals providing at least some aspect of a safety net, the number of overdose deaths and other related health consequences arising from opioid addictions would have even been far greater than actually occurred, and the public outcry and political backlash threatening their profitmaking activities would have come far more swift and far more certain.

20. The statistics are startling. Adult hospitalizations due to opioid misuse or dependence doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.¹⁷

21. Between 2005 and 2014 there was a dramatic increase nationally in hospitalizations involving opioids: the rate of opioid-related inpatient stays increased 64 percent, and the rate of opioid-related emergency department (ED) visits nearly doubled.¹⁸

¹⁶ Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), <https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse>, (last accessed on April 26, 2018).

¹⁷ *Id.*

¹⁸ Audrey J. Weiss, et al, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf>.

22. The average health care costs for opioid abusers were 8 times higher than those of non-abusers.¹⁹

23. The cost to hospitalize those with opioid abuse or dependence problems has more than tripled in a decade, up to nearly \$15 billion in 2012. Similarly, the number of patients hospitalized for the effects of these drugs surged by more than 72% in 2012, although overall hospitalizations during that time stayed relatively flat.²⁰

24. Private insurance is only covering a portion of that. The burden is carried out by the hospitals, the patients and the government programs.²¹ In 2012, hospitals provided almost \$15 billion for opioid related inpatient care, more than double of what they billed in 2002.²² A substantial portion of these costs were under-insured or unreimbursed.

25. In 2012, an average hospital stay for an opioid patient costs about \$28,000, and only about 20% of the discharges related to those incidents were covered by private insurance. The number increased to \$107,000 if there was an associated infection, with merely 14 percent covered by insurance.²³

26. Patients with complex opioid-related histories (medically and psychosocially) often cannot get treatment at skilled nursing facilities if they are discharged by hospitals. As a

¹⁹ Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in *Journal of Managed Care Pharmacy*, Vol. 11, No. 6 July/August 2005, at 469.

²⁰ Marty Stempniak, *Opioids Add to a Sharp Rise in Hospitalizations, Costs*, (May 5, 2016), <https://www.hhnmag.com/articles/7231-opioids-contribute-to-a-sharp-rise-in-hospitalizations-health-care-costs>, (last accessed on April 28, 2018).

²¹ *Id.*

²² Shefali Luthra, *Opioid Epidemic Fueling Hospitalizations, Hospital Costs*, KAISER HEALTH NEWS (May 2, 2016), <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/>.

²³ *Id.*

result, they wind up staying in hospitals longer, so the cost of their care goes up.²⁴

27. The cost of treating opioid overdose victims in hospital intensive care units jumped 58 percent in a seven-year span. Between 2009 and 2015, the average cost of care per opioid admission increased from \$58,000 to \$92,400. This was during a period where the overall medical cost escalation was about 19 percent. This cost increase also highlights a troubling trend: overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.²⁵

B. Impact of Opioids on South Florida Hospitals

28. Due to the Defendants' conduct described in this Complaint, sick opioid patients are placing an increasing strain on an overmatched health care system, particularly in South Florida.

29. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

30. During the 2000s, Florida medical laws allowed physicians to prescribe and dispense pharmaceuticals from their offices. Until 2009, Florida had no prescription-monitoring system. Until then, any pharmacist would fill a prescription. As a result, Florida became a popular destination for out-of-state opioid addicts to get opioids. Addicts from the OxyContin-

²⁴ <https://khn.org/news/opioid-epidemic-fueling-hospitalizations-hospital-costs/> last accessed on April 25, 2018.

²⁵ Casey Ross, *The Cost of Treating Opioid Overdose Victims is Skyrocketing*, STAT NEWS (August 11, 2017), <https://www.statnews.com/2017/08/11/opioid-overdose-costs/>.

wracked regions of Ohio, Kentucky, and West Virginia headed weekly to Florida for doctor visits. **“By 2009, of the top oxycodone-prescribing counties in America, nine were in Florida . . . Broward County had four pain clinics in 2007 and 115 two years later.”**²⁶

31. In 2009, 25% of nationwide shipments of oxycodone were sent to the state of Florida. By 2010, 98 of the 100 doctors in the country who dispensed the highest quantities of oxycodone from their offices were located in Florida.²⁷

32. In 2009 and 2010, Florida Legislature began regulating pain-management clinics and physicians who practice in them. In 2009, Florida finally put in a statewide Prescription Drug Monitoring Program (“PDMP”). It was the last state in the country to do so.²⁸ The program consisted of a network database that was designed to allow doctors and pharmacists to see if patients had multiple prescriptions for the same drug. But, for a variety of reasons, the program did not go into effect as scheduled.²⁹

33. In March of 2010, as part of a multi-jurisdictional investigation, the Federal Drug Enforcement Agency (“DEA”) and police departments in Broward and Palm Beach counties raided the largest pain clinics in Florida.³⁰ On October 1, 2010, Florida law began to require

²⁶ Dreamland, at 243-45. Oxycodone is the generic version of OxyContin.

²⁷ William N. Evans, et al., *How the Reformulation of OxyContin Ignited the Heroin Epidemic*, National Bureau of Economic Research, NBER Working Paper No. 24475, (Issued April 2018), doi: 10.3386/w24475, <http://www.nber.org/papers/w24475>.

²⁸ Dreamland, at 246 (emphasis added).

²⁹ How the Reformulation of Oxycontin ignited the Heroin Epidemic, William N. Evans, et al. NBER Working Paper Series, published in April 2018, at page 40, available at <http://www.nber.org/paper/w24475>.

³⁰ Emily Cohen, *Feds Raid Pain Clinics Suspected of Illegally Distributing Millions of Prescription Drugs*, ABC News (March 8, 2010), <http://abcnews.go.com/Business/PersonalFinance/feds-raid-alleged-pill-mills-florida/story?id=10022791>.

“pain-management clinics” to register with the Florida Department of Health (“DOH”) as a pain-management clinic.³¹

34. In July of 2011, the Florida Governor signed into law HB 7085. That law prohibited most doctors from prescribing and dispensing prescriptions such as OxyContin from their office, and fully funded the PDMP for the first time, nearly two years after that law had been enacted. Florida’s PDMP became operational in September 2011 and on October 17th, doctors could register on the PDMP for the first time.³²

35. Effective July 1, 2018, a new law signed by Governor Scott will bolster Florida’s PDMP by placing a limitation of three days on most opioid medical prescriptions for acute pain, prohibiting pain clinics from advertising that they sell pain pills and from naming the pills, and requiring that the clinics must open their doors for inspections.³³

36. Many opioid addicts relocated to South Florida to be near their supply. By 2002, the human toll taken by the abuse and misuse of prescription narcotics such as OxyContin had become “increasingly alarming.”³⁴ That year, the South Florida Sun-Sentinel reported that its review of medical examined data had found that nearly four hundred people had died from prescription drug overdoses in the area around the cities of Miami, Fort Lauderdale, and Palm

³¹ Troy A. Kishbaugh & Sarah L. Mancebo, *Florida Legislation Regarding Pain Management Clinics*, GrayRobinson (March 5, 2012), http://www.gray-robinson.com/Elerts/03_05_12_Health_Elert_Florida_Legislation_Regarding_Pain_Management_Clinics.pdf.

³² *Id.* at page 42.

³³ Robert Nolin, *32 new Florida laws take effect today*, PALM BEACH POST (April 1, 2012), <https://www.palmbeachpost.com/news/crime--law/new-florida-laws-take-effect-today/cEzcdEcEtFRXM2yd2t4ZPN/>.

³⁴ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail Of Addiction And Death*, 94 (Rodale 2003) (herein after “*Pain Killer*”).

Beach, the area served by Plaintiff West Boca Medical Center and other hospitals. “The vast majority of those deaths involved narcotic painkillers, containing oxycodone or hydrocodone, and many of those who had died had been able to obtain large quantities of painkillers from doctors despite documented histories of drug abuse, the paper reported.”³⁵

37. Drug overdose death rates in Florida have skyrocketed over the past two decades.³⁶ In 2016, 5,725 opioid-related deaths were reported in Florida, which represents a 35% increase from 2015, including, a 28% increase in oxycodone-related deaths.³⁷ Florida also experienced a resurgence in heroin and Fentanyl³⁸ use leading to a significant increase in heroin-related deaths (30% increase) and fentanyl-related deaths (97% increase).³⁹

38. According to a Child Welfare League of America 2017 report, during the year 2015, health care costs related to opioid abuse in Florida reached \$1,246,526,068.⁴⁰ Florida health care costs associated with opioid abuse was the fourth highest among all states, as shown below.

³⁵ *Id.*

³⁶ Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Available at, <http://wonder.cdc.gov/ucd-icd10.html> (last accessed Apr. 17, 2017).

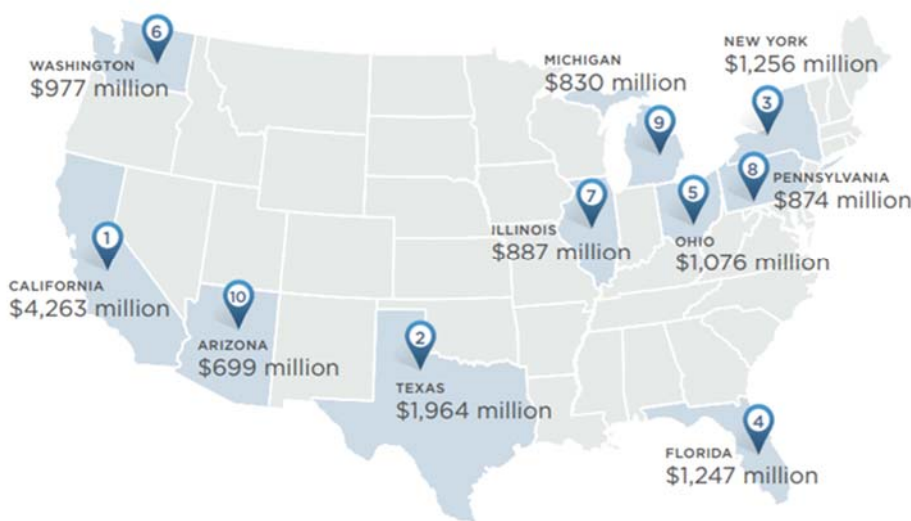
³⁷ *Id.*

³⁸ Fentanyl is manufactured by Manufacturer Defendant Janssen.

³⁹ *Id.*

⁴⁰ Florida’s Children at a Glance, Child Welfare League of America, <http://www.cwla.org/wp-content/uploads/2017/03/FLORIDA-1.pdf>, (last accessed on April 26, 2018).

TOP 10 STATES: TOTAL HEALTH CARE COSTS FROM OPIOID ABU



39. Drug overdose deaths in Palm Beach County and Broward County have continued to rise in recent years.⁴¹

40. Defendants were aware of federal and Florida laws which required hospitals to admit and treat opioid-addicted patients when they engaged in their marketing scheme.

41. The impacts of Defendants' conduct foreseeably include America's hospitals. Under EMTALA, hospitals are not only required to "provide medical screening examination for individuals" that visit their emergency departments for any emergency medical condition, but also to provide treatment to stabilize the medical condition, or appropriately transfer the individual to another hospital. 42 U.S.C. §§ 1395dd (a) & (b). "In general any individual (whether or not eligible for benefits under this subchapter) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—(A) within the staff and facilities available at the hospital, for such further medical

⁴¹ *Id.*

examination and such treatment as may be required to stabilize the medical condition, or (B) for transfer of the individual to another medical facility in accordance with subsection (c).” 42 U.S.C. § 1395dd (b).

42. Florida has its own EMTALA like requirement, Fla.Stat. Ann. §395.1041 - Access to emergency services and care. Florida’s EMTALA statute was enacted in 1988, two years after EMTALA and tracks EMTALA closely.

43. Under EMTALA, “emergency medical condition” means— (A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in— (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part; or (B) with respect to a pregnant woman who is having contractions— (i) that there is inadequate time to effect a safe transfer to another hospital before delivery, or (ii) that transfer may pose a threat to the health or safety of the woman or the unborn child. 42 USC § 1395dd(e)(1).

44. Florida’s “Baker Act,” further requires hospitals to provide treatment for persons who present with symptoms of mental illness. “A person shall not be denied treatment for mental illness and services shall not be delayed at a receiving or treatment facility because of inability to pay.” Florida Statute 394.459 (2)(a). Further, the law requires that “the least restrictive appropriate available treatment be utilized based on the individual needs and best interests of the patient and consistent with optimum improvement of the patient’s condition.” Florida Statute 394.459 (2)(b). “Each person who remains at a receiving or treatment facility for more than 12 hours shall be given a physical examination by a health practitioner authorized by law to give

such examinations, within 24 hours after arrival at such facility.” Florida Statute 394.459 (2)(c).

45. As a result of these statutes, hospitals in Florida must admit opioid addicts, who present themselves in need of intensive care or who display symptoms of mental illness. In addition, if an opioid addict is pregnant, and presents herself for treatment, hospitals also have to provide care for both the opioid-addicted mother and her opioid-addicted baby.

46. “Virtually every hospital I have talked to has been touched by this,” said Bruce Rueben, president of the Florida Hospital Association, a Tallahassee industry group.⁴²

47. As a result of the opioid addiction epidemic in the area which Plaintiff serves, opioid-addicted patients routinely occupy beds in West Boca Medical Center. Opioid-addicted mothers and babies routinely present themselves for admission at its two ERs and occupy beds in the NICU. Many of those patients have no insurance and do not pay for their care.

48. Delray Beach (in Palm Beach County) is at the center of the South Florida overdose epidemic—estimated to have claimed more than 900 lives last year.⁴³ The sheer number of opioid overdoses in South Florida is overwhelming police, firefighters, hospitals and morgues.⁴⁴

49. Costs have been increasing rapidly. In Palm Beach County in 2009, it took 18 months of treatment of sick babies to run up a \$3.4 million hospital bill. By late 2015, costs

⁴²Pat Beall & Mike Stucka, *Cost of Heroin Epidemic Tops \$1 billion a year in Florida*, PALMBEACHPOST (Dec. 17, 2016), <https://www.mypalmbeachpost.com/news/cost-heroin-epidemic-tops-billion-year-florida/WYamI7pzwIHMkFkf3mzY8H/>.

⁴³ Peter Haden, *The Number of Daily Opioid Overdose in South Florida is Overwhelming Police*, PRI (April 20, 2017), <https://www.pri.org/stories/2017-04-20/number-daily-opioid-overdoses-south-florida-overwhelming-police>.

⁴⁴ *Id.*

accelerated to the point that it took just three months to run up the same bill.⁴⁵

50. Palm Beach County Fire and Rescue responded to more than 4,500 overdose calls in 2016,⁴⁶ an average of over 12 overdose calls every day on a 365 day period.

C. Financial Impact of Defendants' Activities on Plaintiff

51. Plaintiff West Boca Medical Center, Inc. was incorporated on February 7, 2001, and does business as West Boca Medical Center. It is a health system serving residents across Palm Beach County, Florida where its main hospital is located, and Broward County, Florida where Plaintiff has a separate emergency room ("ER") facility. At its main location, West Boca Medical Center has a 195-bed facility, including a pharmacy, and ER and a 35-bed Neonatal Intensive Care Unit ("NICU").

52. Plaintiff West Boca Medical Center has purchased and continues to purchase and administer opioids marketed and sold by Defendants.

53. Plaintiff has treated, and continues to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) neonatal treatment in its NICU for babies born opioid-addicted because their mothers were opioid addicts for which treatment is specialized, intensive, complex, and lengthy; and (4) psychiatric and related treatment for opioid users who present as in need of mental health treatment programs.

54. Police in Palm Beach and Broward Counties pick-up opioid-addicted people who appear to have mental health problems and bring them to West Boca Medical Center to "clear" them before they are allowed to enter a mental health facility. West Boca Medical Center has no

⁴⁵ *Id.*

⁴⁶ Bridget O'Brien & Katie Lepri, *Broward, Palm Beach Counties Push Ahead to Sue Big Pharma for Opioid Crisis*, WLRN (Dec. 15, 2017), <http://wlrn.org/post/broward-palm-beach-counties-push-ahead-sue-big-pharma-opioid-crisis>.

dedicated space for such patients, but must make room for them under the Baker Act. So, West Boca Medical Center has to improvise by converting its regular rooms to mental health rooms with security present and attended by staff doctors with the appropriate expertise. These stays often last for days and are expensive and often unpaid.

55. Plaintiff has incurred and continues to incur substantial unreimbursed charges for its treatment of patients with opioid conditions. These patients with opioid-related conditions presented for treatment to Plaintiff as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiff's monetary losses with respect to treatment of these patients are foreseeable to Defendants and are the proximate result of Defendants' acts and omissions previously specified herein.

56. Plaintiff admitted and treated many of these patients as a result of its obligations under EMTALA and the Baker Act. Between April 1, 2016 and September 30, 2017, 629 patients presented to Plaintiff with opioid related conditions. Of those, 416 were admitted for treatment. Those numbers are on the rise.

57. Plaintiff also has incurred and continues to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid addicts. Surgical procedures on opioid addicts have been and are more complicated and costly and require special protective measures and related prescription drugs.

58. Additionally, opioid users have presented and continue to present themselves to Plaintiff claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiff has incurred and continues to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise dealing

with “pill seekers” before their true status can be determined and they can be rejected as patients.

59. The costs incurred by these hospitals are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

60. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid-related conditions going to hospitals for treatment, including Plaintiff. It was also foreseeable to Defendants that Plaintiff would suffer and continues to suffer substantial monetary losses because of the opioid epidemic, since hospitals are on the front-line of treatment for these patients and must bear the additional costs of treating these patients.

61. It was also foreseeable that Defendants would face claims from hospitals for their costs treating opioid-related illnesses. Hospital lien laws enacted in Florida counties by special acts and ordinances and enacted in many other states provide the hospitals with a lien to recover for their costs and services related to any incident that gave rise to injury to the hospital’s patients for the hospital’s charges resulting therefrom.

62. The Defendants have marketed and continue to market their opiate products directly to Plaintiff and other hospitals, and to doctors on staff at those hospitals, and thus Plaintiff was and is a direct customer and victim of the Defendants’ false, deceptive and unfair marketing of opioids described hereafter.

63. As a direct and proximate result of Defendants’ misconduct, Plaintiff has purchased opiates from the Defendants, and used them as falsely and deceptively marketed by Defendants, and suffered damages as a direct and proximate cause of Defendants’ acts as described in this Complaint.

64. Plaintiff brings this civil action to recover monetary losses that have been incurred

as a direct and proximate result of Defendants' false, deceptive, and unfair marketing of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

65. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profit. Such actions were unlawful.

66. Plaintiff also brings this suit against the wholesale distributors and retailers of these highly addictive drugs. The distributors and manufacturers unlawfully breached their legal duties under federal law to monitor, detect, investigate, and report suspicious orders of prescription opiates which allowed the manufacturers' deceptive advertising to result in sales of their products to hospitals, including Plaintiff West Boca Medical Center.

D. The Roles of Defendants in Causing and Perpetuating the Opioid Crisis

67. The Marketing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

68. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have

actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know should be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

69. From the day they made the pills to the day those pills were consumed in each community, these manufacturers had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

70. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

71. Corporate greed and callous indifference to known, serious potential for human suffering have caused this public health crisis. Defendants unleashed a healthcare crisis that has had far-reaching financial, social, and deadly consequences in this country.

72. The Marketing Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more

opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin that purportedly provided twelve hours of pain relief; (8) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

73. The Marketing Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Marketing Defendants for their support of the Marketing Defendants’ marketing messages.

74. The Marketing Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). The Marketing Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Marketing Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

75. Each Marketing Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.⁴⁷

76. In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."⁴⁸

JURISDICTION AND VENUE

77. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

78. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Florida and Ohio and purposefully directed their actions toward these States, consensually submitted to the jurisdiction of these

⁴⁷ See Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf (last accessed April 12, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), <https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines>.

⁴⁸ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, available at <http://turnthetidex.org/> (last accessed April 12, 2018).

States when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with these States necessary to constitutionally permit the Court to exercise jurisdiction.

79. Venue is proper in this District and the Southern District of Florida under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in these Districts and each Defendant transacted affairs and conducted activity that gives rise to the claims for relief in these Districts.

80. Venue is also proper in this District pursuant to Case Management Order No. 1, which provides for direct filing in this Court for any Plaintiff whose case would be subject to transfer to this MDL.⁴⁹

PARTIES

I. PLAINTIFF

81. Plaintiff West Boca Medical Center, Inc. is a Florida corporation, located at 21644 State Road, West Boca, Florida 33428. Plaintiff is a 195-bed, acute-care facility.

II. DEFENDANTS

A. Marketing Defendants

1. Purdue and Associated Companies

82. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

83. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

84. Defendant The Purdue Frederick Company, Inc. is a New York corporation with

⁴⁹ Case Management Order One, Dkt. No. 232, *In re: National Prescription Opiate Litigation*, Case No. 1:17-CV-2804 (Apr. 11, 2018).

its principal place of business in Stamford, Connecticut.

85. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including to Plaintiff. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

86. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million – one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

2. Cephalon and Associated Companies

87. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

88. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

89. Defendant Teva Pharmaceuticals USA, Inc. ("TEVA USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

90. Teva USA and Cephalon, Inc. worked together to manufacture, promote, sell, and distribute opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.”⁵⁰ Fentora has been approved by the FDA only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”⁵¹ In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a \$425 million fine.⁵²

91. Teva USA, and Cephalon, Inc. (collectively Cephalon) work together closely to market and sell Cephalon products in the United States. Since its acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States, through its “specialty medicines” division. Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by

⁵⁰ *Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009)*, ACTIQ PI/Med Guide, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s0301bl.pdf (last accessed April 12, 2018).

⁵¹ *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011)*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s0151bl.pdf (last accessed April 12, 2018).

⁵² Press Release, U.S. Dep’t of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>.

Teva USA, and directs physicians to contact Teva USA to report adverse events.

92. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.⁵³ Teva USA's parent company, Teva Pharmaceuticals Industries, Ltd. lists Cephalon's and Teva USA's sales as its own on its financial reports, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon's specialty sales,” including *inter alia* sales of Fentora.⁵⁴

93. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to herein as “Cephalon.”

94. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact deceptively to promote and maximize the use of opioids.

3. Janssen and Associated Companies

95. Defendant Johnson & Johnson (“J&J”) is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

96. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

97. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen

⁵³ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left) (last accessed April 12, 2018).

⁵⁴ Teva Ltd., Annual Report (Form 20-F), at 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf

Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

98. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. is or had been part of J&J's opium processing by making active pharmaceutical ingredients ("APIs") for opioid painkillers.

99. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

100. J&J, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho- McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

101. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

102. Janssen made thousands of payments to physicians nationwide, including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

103. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. Johnson & Johnson imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J.⁵⁵ Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "*Ethical Code for the Conduct of Research and Development*," names only J&J and does not mention Janssen anywhere within the document. The "*Ethical Code for the Conduct of Research and Development*" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

104. The "*Every Day Health Care Compliance Code of Conduct*" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "*Pharmaceutical Companies of Johnson & Johnson*" and as one of the "*Johnson & Johnson Pharmaceutical Affiliates*." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case. J&J made payments to thousands of physicians nationwide, including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of

⁵⁵ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

opioids.

4. Endo and Associated Companies

105. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

106. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

107. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, “Endo”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

108. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, generic versions of oxycodone, oxymorphone, hydromorphone and hydrocodone in the United States. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo’s total revenue in 2012. On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a “serious outbreak” of HIV and hepatitis C due to abuse of the drug after the reformulation of Opana from a nasal spray to an injectable.⁵⁶ In response to the FDA’s request, Endo removed Opana ER from the market in July 2017.⁵⁷ Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone,

⁵⁶ Press Release, U.S. Food & Drug Administration, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁵⁷ Press Release, Endo International PLC, Endo Provides update on Opana ER (July 6, 2017), <http://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er>.

hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

109. Endo made thousands of payments to physicians nationwide, including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

5. Insys Therapeutics, Inc.

110. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys.

111. Insys made thousands of payments to physicians nationwide, including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

112. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

113. In 2016, Insys made approximately \$330 million in net revenue from Subsys.

Insys promotes, sells, and distributes Subsys throughout the United States, and Plaintiff.

114. Insys' founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

6. Mallinckrodt Entities

115. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC (together with Mallinckrodt plc, “Mallinckrodt”) is a Delaware corporation with its headquarters in Hazelwood, Missouri. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and to Plaintiff. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

116. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

117. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA’s entire annual quota for controlled substances that it

manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.⁵⁸

118. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

119. Among the drugs Mallinckrodt manufactures or has manufactured are the following: Schedule II: Exalgo (Hydromorphone hydrochloride, extended release), Roxicodone (Oxycodone hydrochloride), Xartemis XR (Oxycodone hydrochloride and acetaminophen), Methadose (Methadone hydrochloride), Generic (Morphine sulfate, extended release, Morphine sulfate oral solution, Fentanyl transdermal system, Oral transmucosal fentanyl citrate, Oxycodone and acetaminophen, Hydrocodone bitartrate and acetaminophen, Hydromorphone hydrochloride, Hydromorphone hydrochloride, extended release, Oxymorphone hydrochloride, Methadone hydrochloride. Schedule III: Buprenorphine and naloxone. Unscheduled: Naltrexone hydrochloride.

120. Mallinckrodt made thousands of payments to physicians nationwide, including in Florida, ostensibly for activities including participating on speakers bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids

⁵⁸ Mallinckrodt plc 2016 Form 10-K.

7. Actavis and Associated Companies

121. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

122. Defendant Actavis plc acquired Defendant Allergan plc in March 2015, however the combined company changed its name to Allergan plc in January 2013.

123. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then changed the name to Actavis plc in October 2013.

124. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

125. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

126. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

127. Each of these Defendants is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States.

128. Defendant Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, “Actavis”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States, including to Plaintiff.

129. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

130. Actavis made thousands of payments to physicians nationwide including in Florida, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact deceptively to promote and maximize the use of opioids.

131. Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as "Marketing Defendants."

B. Distributor Defendants

132. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing Plaintiff's community.

1. AmerisourceBergen Drug Corporation

133. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including to Plaintiff.

134. AmerisourceBergen is the eleventh largest company by revenue in the United

States, with annual revenue of \$147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

135. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."⁵⁹

2. Cardinal

136. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal generated revenues of \$121.5 billion.

137. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over \$120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including Florida, and has distributed opioids nationwide.

3. McKesson Corporation

138. McKesson is a Delaware corporation with its principal place of business located in San Francisco, California.

139. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America, including to

⁵⁹ AmerisourceBergen, 2016 Summary Annual Report, <http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb> (last accessed April 12, 2018).

Plaintiff.

140. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 billion

141. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”⁶⁰

142. According to the 2017 Annual Report, McKesson’s “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

143. McKesson Corporation (“McKesson”) is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country.

144. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor.”

⁶⁰ McKesson, Annual Report, http://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf (last accessed April 12, 2018).

145. McKesson is the largest pharmaceutical distributor in the United States.

146. McKesson has more than 40,000 customers nationally.

147. Collectively, McKesson, AmerisourceBergen, and Cardinal account for 85% of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

148. Cardinal, McKesson, and AmerisourceBergen are collectively referred to as the “Distributor Defendants.”

C. National Retail Pharmacies

1. CVS Health Corporation

149. Defendant CVS Health Corporation (“CVS”) is a Delaware corporation with its principal place of business in Rhode Island. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Florida and Palm Beach County.

2. The Kroger Co.

150. Defendant The Kroger Co. (“Kroger”) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates 2,268 pharmacies in the United States, including in Florida. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Florida and Palm Beach County.

3. ~~Rite Aid of Maryland, Inc.~~

151. ~~Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid Atlantic Customer Support Center, Inc. (“Rite Aid”), is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid distributed prescription opioids throughout the United States, including in Florida and Palm Beach County.~~

4. Walgreens Boots Alliance, Inc.

152. Defendant Walgreens Boots Alliance, Inc., also known as Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Florida and Palm Beach County.

5. Wal-Mart Inc.

153. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in Florida and Palm Beach County.

154. Collectively, Defendants CVS, Kroger, ~~Rite Aid~~, Walgreens, and Wal-Mart are referred to as “National Retail Pharmacies.” Additionally, the Distributor Defendants and the National Retail Pharmacies are collectively referred to as the “Supply Chain Defendants.”

155. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale and/or dispensing of opioids.

D. Defendants’ Agents

156. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’ officers, agents, employees, or other representatives while actively engaged in the management of Defendants’ affairs within the course and scope of their duties and employment, and/or with Defendants’ actual, apparent, and/or ostensible authority.

CONTINUING VIOLATIONS

157. This Complaint alleges a continuing course of conduct (including conduct within

the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiff can recover for damages that it suffered during any applicable limitations period.

FACTUAL BACKGROUND

I.THE HISTORY OF OPIOIDS

126. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, which has been used to relieve pain for centuries.

127. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.⁶¹

128. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

129. Since passage of the Controlled Substances Act ("CSA") in 1970, 21 U.S.C. § 801, et seq., opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety.

130. Opioids generally have been categorized as Schedule II, although some are classified as Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21

⁶¹ Martin Booth, *Opium: A History*, at 20 (Simon & Schuster Ltd. 1996).

U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

131. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as hospitals, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

132. The synthetic opioid fentanyl has been a driving force behind the nation's opioid epidemic, killing tens of thousands of Americans in overdoses. Two states are now pushing to use the drug's powerful properties to execute prisoners on death row.⁶²

133. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.⁶³

134. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.⁶⁴

⁶² William Wan & Mark Berman, *States to Try New Ways of Executing Prisoners. Their Latest Idea? Opioids.*, THE WASHINGTON POST (Dec. 9, 2017), https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879_story.html?utm_term=.c7048831bfcd.

⁶³ Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, doi: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁶⁴ Centers for Disease Control and Prevention, *Heroin Overdose Data*,

135. According to the CDC, opioids are responsible for the majority of drug overdoses today.⁶⁵ Additionally, opioid overdose have quadrupled nationally since 1999.⁶⁶

136. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. Throughout this Complaint, “addiction” refers to the entire range of substance abuse disorders.⁶⁷ Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

II. THE OPIOID EPIDEMIC

137. Prescription opioids have become widely prescribed. In 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.⁶⁸

138. Despite the large number of prescriptions, recent studies have concluded that treatment with opioids is not superior to treatment with non-opioid medications for improving pain-related function.⁶⁹ Even for patients presenting to the emergency room with acute extremity pain, there is no significant or clinically important difference in pain reduction at 2 hours among

<https://www.cdc.gov/drugoverdose/data/heroin.html> (last accessed April 12, 2018).

⁶⁵ *Id.*

⁶⁶ Centers for Disease Control and Prevention, *Drug Overdose Death Data* <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed April 12, 2018).

⁶⁷ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2013).

⁶⁸ Katherine M. Keyes et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 *Am. J. Pub. Health* e52-e59 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3935688/>.

⁶⁹ Erin E. Krebs, M.D., et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, 319 *JAMA* 872-882 (2018), doi: 10.1001/jama.2018.0899, <https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true>.

single-dose treatment with ibuprofen and acetaminophen or with three different opioid and acetaminophen combination analgesics.⁷⁰

139. In 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels.

The News Release noted:

- a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
- b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
- c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
- d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
- e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
- f. Almost 5,500 people start to misuse prescription painkillers every day.⁷¹

140. The CDC has also identified addiction to prescription pain medication as the

⁷⁰ Andrew K. Chang, M.D., et al., *Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, 318 JAMA 1661-1667 (2017), DOI: 10.1001/jama.2017.16190, <https://jamanetwork.com/journals/jama/article-abstract/2661581?widget=personalizedcontent&previousarticle=2673971&redirect=true>.

⁷¹ See Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.⁷² According to a recent study, among young urban heroin users, 86% used opioid pain relievers prior to using heroin.⁷³

141. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.⁷⁴

142. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.⁷⁵

143. The National Institute on Drug Abuse identifies misuse and addiction to opioids as “a serious national crisis that affects public health as well as social and economic welfare.”⁷⁶

The economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the

⁷² See Centers for Disease Control and Prevention, *Today’s Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last accessed April 12, 2018).

⁷³ Nat’l Inst. on Drug Abuse, *Prescription Opioids and Heroin* (Jan. 2018), <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf>.

⁷⁴ See Rudd et al., Centers for Disease Control and Prevention, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015* (Dec. 30, 2016), Morbidity & Mortality Wkly. Rep. 2016; 65; 1445-1452, DOI: <http://dx.doi.org/10.15585/mmwr.mm655051e1>, available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁷⁵ See Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMr1507771, <http://www.nejm.org/doi/full/10.1056/NEJMr1507771>, (hereinafter “Volkow and McLellan”).

⁷⁶ *Id.*

costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.⁷⁷

144. In 2016, the President of the United States officially declared an opioid and heroin epidemic.⁷⁸

III. OPIOIDS IN CONGRESS

145. Congressional interest in the opioid crisis is intense and proceeding at a vigorous pace. During the current congressional term, multiple committees in the House and Senate conducted dozens of hearings exploring the issue from almost every angle, including effects on the health care system, people and their communities, law enforcement, workplaces, schools, and the Native American community. Two congressional committees are taking the lead to enact legislation to address the crisis: the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor and Pensions (HELP). In April 2018, the HELP Committee passed a bipartisan, comprehensive bill to address the opioid crisis and a Subcommittee of the Energy and Commerce Committee passed over 50 bills to combat the crisis, most on a bipartisan vote.

IV. THE MARKETING DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

146. The opioid epidemic did not happen by accident.

147. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or

⁷⁷ *Id.* (citing at note 2, Florence CS, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013* (Oct. 2016), 54 Med. Care 901-906 (2016), DOI: 10.1097/MLR.0000000000000625, available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>).

⁷⁸ See Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week"), available at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-22/pdf/2016-22960.pdf>.

for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

148. Each Marketing Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

149. The Marketing Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians that the Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

150. The Marketing Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.⁷⁹ In an open letter to the nation's physicians in August 2016, the then U.S.

⁷⁹ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, FORTUNE (Nov. 9, 2011), <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers Hooked on \$10bn Opioid Habit*, FINANCIAL TIMES (Aug. 10, 2016).

Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors ... [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”⁸⁰ This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

151. The Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

152. As alleged throughout this Complaint, Defendants’ conduct created a public health crisis and a public nuisance.

153. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; and (c) making naloxone widely available so that overdoses are less frequently fatal.

154. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that

⁸⁰ Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, available at <http://turnthetidex.org/> (last accessed April 12, 2018).

has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer protection laws and regulations. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

V. EACH MARKETING DEFENDANT USED MULTIPLE AVENUES TO DISSEMINATE THEIR FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS.

155. The Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. The Marketing Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's communities.

156. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by the drug manufacturers' corporate headquarters. This comprehensive approach ensures that the Marketing Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Marketing Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

157. The Marketing Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the

company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Marketing Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

A. Direct Marketing

158. The Marketing Defendants' misrepresentations fall into the following nine categories:

- a. The risk of addiction from chronic opioid therapy is low;
- b. To the extent there is a risk of addiction, it can be easily identified and managed;
- c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;
- d. Opioid withdrawal can be avoided by tapering;
- e. Opioid doses can be increased without limit or greater risks;
- f. Long-term opioid use improves functioning;
- g. Alternative forms of pain relief pose greater risks than opioids;
- h. A version of Oxycontin marketed by Purdue was effective in providing 12 hour pain relief; and
- i. New formulations of certain opioids successfully deter abuse.

159. Each of these propositions was false. The Marketing Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

160. The categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing

effort, not as a checklist for assessing each Marketing Defendant's liability. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Marketing Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Marketing Defendant.

1. Falsehood #1: The risk of addiction from chronic opioid therapy is low

161. Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

162. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

163. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at

recommended dose,”⁸¹ and the risk substantially increases with more than three months of use.⁸²

As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).⁸³

a. Purdue’s misrepresentations regarding addiction risk

164. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine (“NEJM”) in 1980.

165. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids.⁸⁴ They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

⁸¹ FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

⁸² CDC Guideline at 21.

⁸³ *Id.* at 2.

⁸⁴ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

166. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.⁸⁵

167. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.⁸⁶ Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

168. In 1996, Defendant Purdue made a deal with Pharmaceutical giant, Abbott Laboratories, under which Abbott’s sales force would promote Purdue’s lead opioid, OxyContin,

⁸⁵ *Pain Killer*, supra n. 34, at 174.

⁸⁶ J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New. Eng. J. Med. 123 (1980).

in hospitals.

169. Purdue specifically used the Porter and Jick letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos says “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.”⁸⁷ Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)⁸⁸

170. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.⁸⁹

171. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the

⁸⁷ Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI>, (last accessed Jan. 31, 2018) (emphasis added).

⁸⁸ Keefe, *Empire of Pain*.

⁸⁹ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

opiate manufacturers convince front-line doctors that addiction is not a concern.”⁹⁰

172. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”⁹¹

173. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”⁹²

174. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called “*A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.*” In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’?,” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes

⁹⁰ *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), <https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

⁹¹ Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), <http://documents.latimes.com/oxycontin-press-release-1996/>.

⁹² *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

are clear and the effects are beneficial, not harmful.

175. Sales representatives marketed OxyContin as a product “to start with and to stay with.”⁹³ Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!”⁹⁴ According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”⁹⁵

176. Purdue, through its unbranded website Partners Against Pain,⁹⁶ stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk also appears to be low when opioids are dosed properly for chronic, non-cancer pain.”⁹⁷

⁹³ Keefe, *Empire Of Pain*.

⁹⁴ *Pain Killer*, supra n. 34, at 102.

⁹⁵ *Id.*

⁹⁶ *Partners Against Pain* consists of both a website, styled as an “advocacy community” for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin’s addictiveness by claiming: “Drug addiction means using a drug to get ‘high’ rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.”

⁹⁷ CHI 166069.

177. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."⁹⁸ May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

178. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

179. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

180. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001, to "provide comments and suggestions on a Risk Management program for OxyContin." Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin's label. Purdue acknowledged that it was aware of abuse of OxyContin

⁹⁸ David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), *The New Yorker* (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin's label; Dr. Cynthia McCormick, then director of the FDA division overseeing pain medication, declared that "'major overhaul is my message.' The prescribing of OxyContin is creeping into a whole population of people where it doesn't belong. Just rewriting the abuse and dependence section won't help much, that part of the insert is not a pivot point."

181. Another FDA participant asked that Purdue "refocus our promotional materials and make the risks of abuse and diversion more prominent." In short, the FDA advised Purdue "that the information put in the label back at the time of product approval did not adequately address the risks associated with this product and this needs to be corrected."

182. In 2001, Purdue revised the indication and warnings for OxyContin, but did not go nearly as far as the FDA recommended or the known risks of the product demanded. While Purdue agreed to "consider" changes to its label, it also expressed a reluctance to make significant changes not required for other prescription opioids. Dr. McCormick noted that the issues discussed at the meeting were specific to OxyContin and that, while the Agency would talk with Purdue's competitors, "'we have a problem here and now with OxyContin.' In due time other manufacturers will be contacted but the first problem is this product."

183. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was

not abused. Purdue announced the label changes in a letter to health care providers but did not, as the FDA suggested, issue “a Medguide for patients on the risks of overdose and the abuse of opioids as well as risks for use by others than those for whom it was prescribed” or undertake the recommended promotional effort to educate patients about the potentially fatal risks of OxyContin.

184. The FDA also informed Purdue what Purdue already knew, as noted above—that “there is a perception that oxycodone is safer than morphine.” A representative from the FDA’s Division of Drug Marketing, Advertising and Communications echoed this, calling for an “extensive educational effort to consumers and health care practitioners” to “correct a misconception that [OxyContin] is different than morphine.” In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Purdue never undertook that effort.

b. Endo’s misrepresentations regarding addiction risk

185. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

186. Until April 2012, Endo’s website for Opana, www.opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

187. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo’s training materials for its sales representatives in 2011 also prompted sales representatives to answer “true” to the statement that

addiction to opioids is not common.⁹⁹

188. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control (“NIPC”)¹⁰⁰ and its website *Painknowledge.com*, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

189. Another Endo website, *PainAction.com*, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

190. A brochure available on *Painknowledge.com* titled “*Pain: Opioid Facts*,” an Endo- sponsored NIPC, stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question—“What should I know about opioids and addiction?”—by focusing on explaining what addiction is (“a chronic brain disease”) and is not (“Taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online.

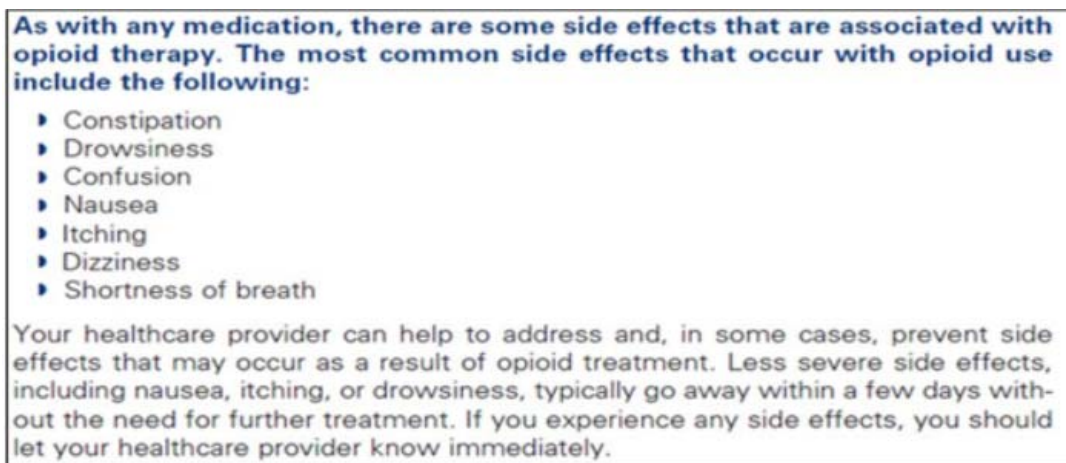
191. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health care providers who treat people with pain agree that most people do not develop an

⁹⁹ ENHAG 82459.

¹⁰⁰ Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

addiction problem.” A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.¹⁰¹

192. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on Painknowledge.com, omitted addiction from the “common risks” of opioids, as shown below:



c. Janssen’s misrepresentations regarding addiction risk

193. Janssen likewise misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let’s Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding addiction.” (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen’s trademark and copy approved by Janssen.¹⁰²)

194. The *Let’s Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug seeking,” “clock watching,” and “even illicit drug

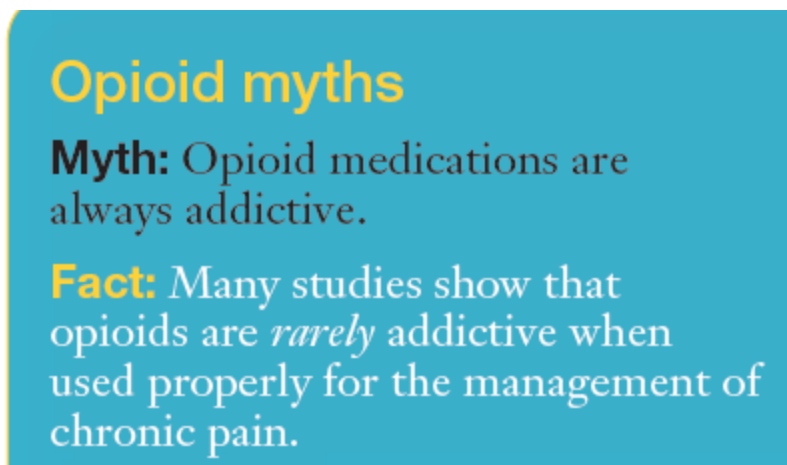
¹⁰¹ ENHAG 82459; ENDO-CHI-LIT-00195455.

¹⁰² JAN00017219.

use or deception” with undertreated pain which can be resolved with “effective pain management.” In August 2009, a “12-month review” of the *Let’s Talk Pain* website manuscript confirmed that the website’s contents included statements regarding pseudoaddiction and illustrated Janssen’s control over the website and awareness of its contents.¹⁰³

195. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”¹⁰⁴

196. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Until recently, this guide was still available online.



197. Janssen’s website for Duragesic included a section addressing “Your Right to

¹⁰³ JAN00006867.

¹⁰⁴ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

198. According to an internal marketing assessment, Janssen sales representatives were trained to emphasize that Nucynta ER had fewer side effects than other opioids, though, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that, this was an untrue and unsubstantiated superiority claim.¹⁰⁵

199. Janssen also conducted a research study on prescribers regarding the visual aids for the marketing of Nucynta ER. Doctors reportedly were interested that Nucynta was described as appropriate for patients at risk for addiction and to avoid addictive narcotics for young people. Additionally, doctors identified the advantages of Nucynta, which included that it was potentially less addicting than other opioids and had a lower street value.¹⁰⁶

200. Janssen also published a patient guide, *Patient Booklet Answers to Your Questions – Duragesic*, which stated that “Addiction is relatively rare when patients take opioids appropriately.”¹⁰⁷

201. Janssen recognized that this misrepresentation was particularly important to payers, who had a “negative” reaction to covering an addictive drug for a chronic condition for which non-narcotic drugs were available.¹⁰⁸

d. Cephalon’s misrepresentations regarding addiction risk

202. Cephalon sponsored and facilitated the development of a guidebook, *Opioid*

¹⁰⁵ JAN00127366.

¹⁰⁶ JAN00013583, ia0044.

¹⁰⁷ JAN00222296.

¹⁰⁸ JAN00017025.

Medications and REMS: A Patient's Guide, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.”

Similarly, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

203. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the non-cancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to under treatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.¹⁰⁹

204. An internal “educational” document claimed that “in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon.” The document continued, “Like patients, caregivers may need reassurance that few people using opioids for a legitimate medical reason become addicted to the drug, and that physical dependence to a drug is easily overcome through scheduled dosing decreases...”¹¹⁰ In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that this Cephalon “learning module” was used to train sales representatives for their

¹⁰⁹ Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <http://www.medscape.org/viewarticle/449803>, (last accessed Oct. 10, 2017).

¹¹⁰ TEVA_CHI_00015258.

interactions with prescribers.

e. Actavis's misrepresentations regarding addiction risk

205. Through its “Learn More about customized pain control with Kadian,” material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is “less likely” to happen in those who “have never had an addiction problem.” The piece goes on to advise that a need for a “dose adjustment” is the result of tolerance, and “not addiction.”¹¹¹

206. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to “predisposing factors” like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the under treatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.¹¹²

207. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential.¹¹³ Actavis's sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors

¹¹¹ ACTAVIS0006823.

¹¹² ACTAVIS0205095.

¹¹³ ACTAVIS0584540.

associate Kadian with less abuse and no highs, in comparison to other opioids.¹¹⁴ Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.¹¹⁵

208. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that, Actavis had no studies to suggest it was.

f. Mallinckrodt's misrepresentations regarding addiction risk

209. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

¹¹⁴ ACTAVIS0584610.

¹¹⁵ ACTAVIS0361609 12/2010 Marketing; ACTAVIS0192847 9/13/2012 (see p.3)

210. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” The “C.A.R.E.S. Alliance” itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

211. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.” “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- c. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- d. “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- e. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”
- f. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

212. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

213. Marketing Defendants’ suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

2. Falsehood #2: To the extent there is a risk of addiction, it can be easily identified and managed

214. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely

monitor those patients.

215. Purdue shared its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. Janssen, on its website PrescribeResponsibly.com, states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors.¹¹⁶ The website, which directly provides screening tools to prescribers for risk assessments,¹¹⁷ includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.¹¹⁸

216. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed” and counseled patients that opioids “give [pain patients] a quality of life we deserve.”

217. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

218. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening

¹¹⁶ Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2, 2015).

¹¹⁷ Risk Assessment Resources, <http://www.prescriberesponsibly.com/risk-assessment-resources> (last accessed April 28, 2018).

¹¹⁸ *Id.*

tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

219. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

220. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speaker’s bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (ORT) created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to Endo-supported websites, as well.

221. There are three fundamental flaws in the Marketing Defendants’ representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

3. Falsehood #3: Signs of addictive behavior are “pseudoaddiction,” requiring more opioids

222. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term “pseudoaddiction,” which he characterized as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”¹¹⁹ In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

223. In the materials and outreach they produced, sponsored, or controlled, the Marketing Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

224. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Fishman and discussed in more detail below, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

225. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *PartnersAgainstPain.com*, in 2005, and circulated this

¹¹⁹David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>. (“Iatrogenic” describes a condition induced by medical treatment.)

pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain.

226. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers.¹²⁰ Purdue’s *Pain Management Kit* is another example of publication used by Purdue’s sales force that endorses pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking behavior.” In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the kit was in use from roughly 2011 through at least June 2016.

227. Similarly, internal documents show that Endo trained its sales representative to promote the concept of pseudoaddiction. A training module taught sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state that: “The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient’s opioid dose to increase pain relief.”

228. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.¹²¹

229. Endo itself has repudiated the concept of pseudoaddiction. In finding that “[t]he

¹²⁰ Source Varley 3-1364 (NH).

¹²¹ Source Stands 3817.

pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents,” the New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”¹²² Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

230. Janssen sponsored, funded, and edited a website called Let’s Talk Pain, which in 2009 stated “pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012. Janssen also currently runs a website, *Prescriberresponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.”¹²³

231. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a KOL discussed below, admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too

¹²² Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

¹²³ Howard Heit, MD, FACP, FASAM, & Douglas Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, <http://www.prescriberresponsibly.com/articles/before-prescribing-opioids>, (last accessed Apr. 28, 2018).

much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. Falsehood #4: Opioid withdrawal can be avoided by tapering

232. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient’s dose to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

233. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient’s opioid dose over ten days.

234. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

235. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that “Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation,” but the guide did not disclose the significant hardships that often accompany cessation of use.

236. To this day, the Marketing Defendants have not corrected or retracted their

misrepresentations regarding tapering as a solution to opioid withdrawal.

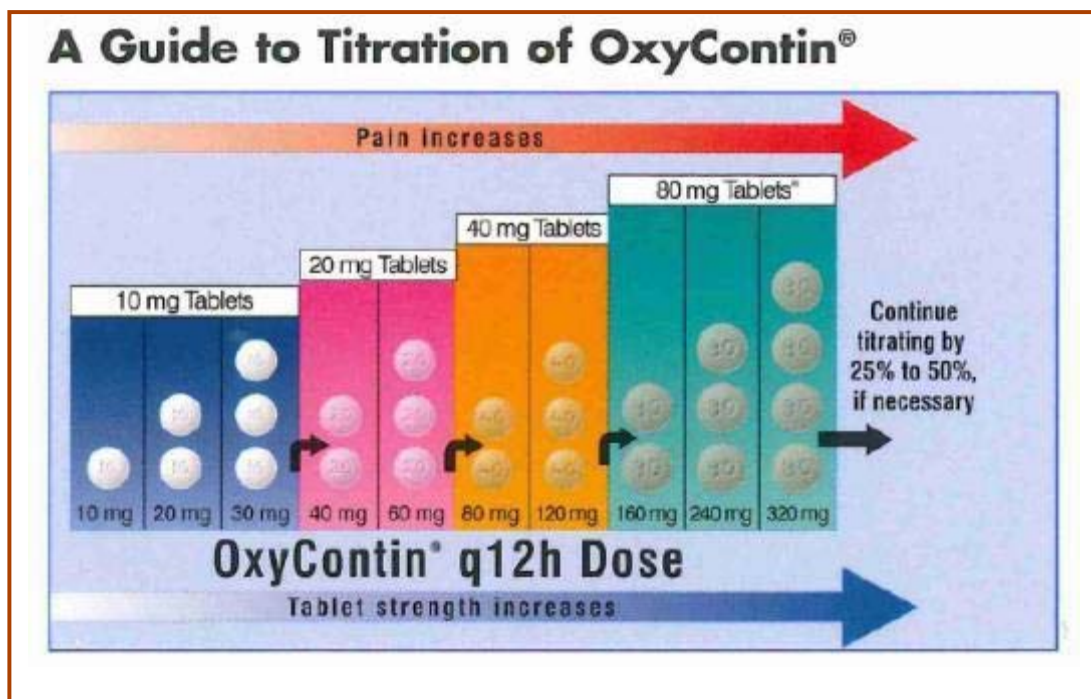
5. Falsehood #5: Opioid doses can be increased without limit or greater risks

237. In materials they produced, sponsored or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that they omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

238. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

239. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."¹²⁴ And the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dose up to 320 mg:

¹²⁴ *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.



240. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."

The next week the representative would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Stronger doses were more expensive and increased the likelihood of addiction.

241. These misrepresentations were particularly dangerous. Opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

242. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin,

however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”¹²⁵

243. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

244. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased . . . You won’t ‘run out’ of pain relief.”

245. According to internal documents, Janssen sales representatives were trained to explain to physicians that patients’ pain was reduced at higher doses and that they were undertreating pain by prescribing lower doses. For example, a 2012 *Nucynta ER Messaging Evolution Full Report* instructs sales representatives to overcome primary care provider’s objections to high doses.¹²⁶

246. Higher dose prescribing was particularly important to Janssen because it knew that doctors did not believe that Nucynta ER provided adequate or equivalent pain relief. A few

¹²⁵ Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://web.archive.org/web/2/https://www.fda.gov/downloads/Drugs/DrugSafety/20y/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf>, (last modified Nov. 2010).

¹²⁶ JAN00019608 (prepared by Research Partnership).

of the doctors who participated in the study voiced concerns over prescribing higher doses. In response, sales representatives were trained to address concerns by emphasizing approved dosing ranges.¹²⁷

247. Marketing Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

6. Falsehood #6: Long-term opioid use improves functioning

248. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids for patients’ function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

249. Janssen, for example, promoted Duragesic as improving patients’ functioning and work productivity through an ad campaign that included the following statements: “[w]ork, uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] . . . physical and social functioning.”

250. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained

¹²⁷ *Id.*

release morphine... We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the “life uninterrupted” message in promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.¹²⁸

251. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users’ function. This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”¹²⁹

252. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

253. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more

¹²⁸ *Pain Killer*, supra n. 34 at 281.

¹²⁹ Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, WALL STREET JOURNAL (Jan. 23, 2003, 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

effectively.

254. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

255. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

256. In addition, Janssen’s *Let’s Talk Pain*, website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

257. Endo’s NIPC website, *Painknowledge.com*, claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

258. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

259. Mallinckrodt’s website, in a section on responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”¹³⁰

260. The Marketing Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life.¹³¹ Based upon a review of the existing scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or

¹³⁰ Mallinckrodt Pharmaceuticals, Responsible Use, <http://www.mallinckrodt.com/corporate-responsibility/responsible-use>, (last accessed Apr. 28, 2018).

¹³¹ The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis’ opioid, Kadian, had an “overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc’ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that “patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”). The FDA’s warning letters were available to Defendants on the FDA website.

function with long-term use.”¹³²

261. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had “consistently poor results,” and “several studies have showed that Opioids for chronic pain may actually worsen pain and functioning . . .”¹³³ along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

262. On the contrary, the available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.”¹³⁴ According to the CDC, “for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”¹³⁵

¹³² CDC Guideline at 20.

¹³³ Thomas Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med., 4/21/16, at 1503.

¹³⁴ CDC Guideline at 2, 18.

¹³⁵ Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, at 1503, 374 New Eng. J. Med. 1501-1504 (April 21, 2016), doi:

263. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.”¹³⁶ In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.¹³⁷ Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.¹³⁸ Yet, Marketing Defendants have not acknowledged, retracted, or corrected their false statements.

7. Falsehood #7: Alternative forms of pain relief pose greater risks than opioids

264. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription non-steroidal anti-

10.1056/NEJMp1515917, <http://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

¹³⁶ Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at <http://www.nbcms.org/en-us/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>

¹³⁷ Jeffrey Dersh, et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) *Spine* 2219-27 (Sept. 15, 2008).

¹³⁸ Franklin, GM, et al., *Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 *Spine* 199, 201-202 (Jan. 15, 2008) doi: 10.1097/BRS.0b013e318160455c, <https://www.ncbi.nlm.nih.gov/pubmed/18197107>.

inflammatory drugs (“NSAIDs”).

265. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of hyperalgesia, a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;”¹³⁹ hormonal dysfunction;¹⁴⁰ decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;¹⁴¹ neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.¹⁴²

266. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.¹⁴³

¹³⁹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

¹⁴⁰ H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), <https://www.ncbi.nlm.nih.gov/pubmed/14622741>.

¹⁴¹ See Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi: 10.1093/eurpub/cku120, <https://www.ncbi.nlm.nih.gov/pubmed/25085470>.

¹⁴² Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass’n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, <https://jamanetwork.com/journals/jama/fullarticle/1105046>.

¹⁴³ Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004), <https://www.ncbi.nlm.nih.gov/pubmed/14704592>.

267. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009) that listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness,” which the brochure claims will go away, and constipation.

268. Endo’s NIPC website, *Painknowledge.org*, contained a flyer called “Pain: Opioid Therapy.” This publication listed opioids’ adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

269. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.”¹⁴⁴ The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.¹⁴⁵

270. To help allay these concerns, Endo emphasized the risks of NSAIDs as an

¹⁴⁴ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf, (link no longer available).

¹⁴⁵ *Id.*

alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

271. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

272. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.¹⁴⁶

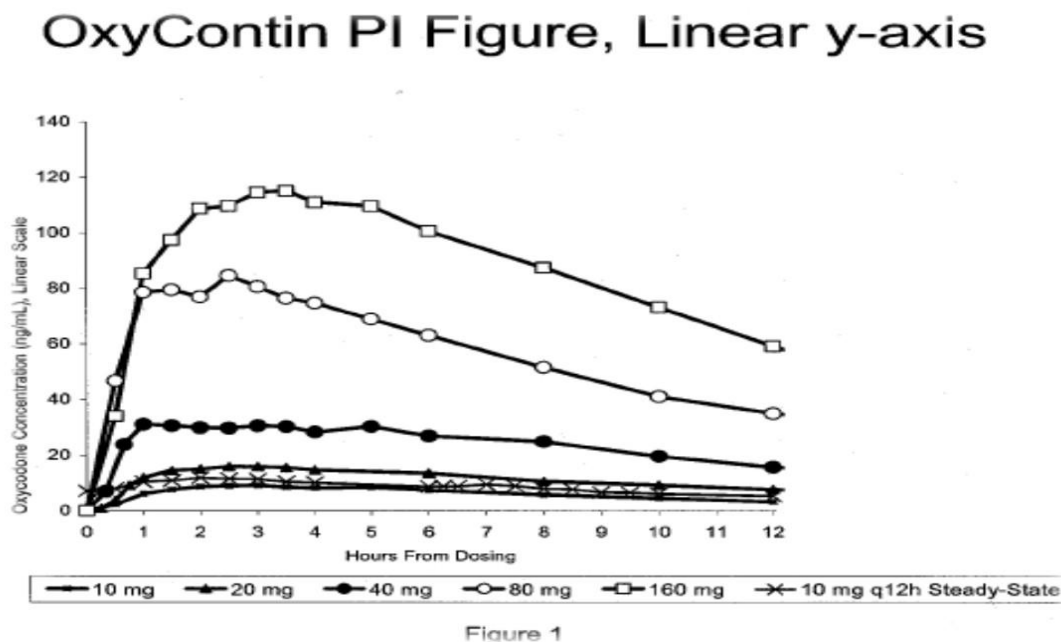
8. Falsehood #8: OxyContin provides twelve hours of pain relief

273. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provided the basis for both Purdue's patent and its market niche, allowing it to both protect and

¹⁴⁶ M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. See also J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

274. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials.



275. The reduced release of the drug over time means that the OxyContin no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

276. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an

immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.)

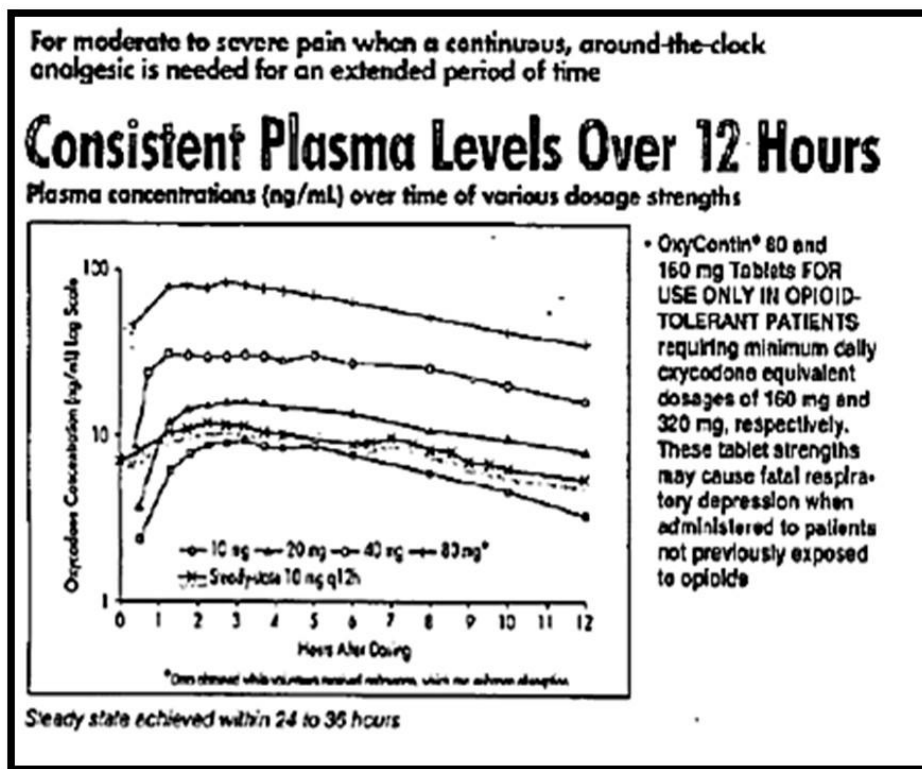
277. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.”¹⁴⁷ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

278. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

279. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-

¹⁴⁷ Harriet Ryan, et al., ‘You Want a Description of Hell?’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



280. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h

dosing was emphasized as the most important benefit.”¹⁴⁸

281. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the LOS ANGELES TIMES, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”¹⁴⁹

282. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two was set out in Purdue’s internal documents as early as 1999, and is apparent from MEDWATCH Adverse Event reports for OxyContin.

283. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

¹⁴⁸ Purdue Meeting Memo, *OxyContin launch*, LOS ANGELES TIMES (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

¹⁴⁹ CDC Guideline at 16.

284. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses.”¹⁵⁰ One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”¹⁵¹

285. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue’s competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

9. Falsehood #9: New formulations of certain opioids successfully deter abuse

286. Rather than take the widespread abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold “abuse-deterrent formulations” (“ADF”) opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants’ false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less

¹⁵⁰ Southern Region Memo to Mr. B. Gergely, *Sales manager on 12-hour dosing*, LOS ANGELES TIMES (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>

¹⁵¹ Harriet Ryan, et al., ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*, LOS ANGELES TIMES (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

subject to abuse than other opioids.

287. The CDC Guideline confirms that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes.” Tom Frieden, the former Director of the CDC, reported that his staff could not find “any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death.”

a. Purdue’s deceptive marketing of reformulated OxyContin and Hysingla ER

288. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

289. Purdue introduced reformulated ADF OxyContin shortly before generic versions of OxyContin were to become available. By so doing, Purdue anticipated and countered a threat to its market share and the price it could charge for OxyContin. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis.

290. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids.

Specifically, Purdue sales representatives:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that its ADF opioids are non-addictive or less addictive,
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

291. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

292. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with.

293. In 2009, the FDA noted in permitting ADF labeling that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)". In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

294. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including

heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

295. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were more harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

296. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

297. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

298. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated

product has a meaningful impact on abuse.”¹⁵² In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin’s ADF properties reduced abuse or misuse.

299. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue’s ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s ADF opioids are being abused in large numbers. Purdue’s recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

b. Endo’s deceptive marketing of reformulated Opana ER

300. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.¹⁵³

301. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower “bioavailability” than other opioids, meaning that the active pharmaceutical ingredient (the “API” or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER’s API is released into the patient’s bloodstream

¹⁵² Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

¹⁵³ ENDO-CHI_LIT-00141071.

relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

302. Endo knew by July 2011 that “some newer statistics around abuse and diversion are not favorable to our product.”¹⁵⁴

303. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

304. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims “may provide a false sense of security since the product may be chewed and ground for subsequent abuse.” In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that “[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction.”

305. Further, a January 4, 2011, FDA Discipline Review letter made clear to Endo that “[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's “INTAC” technology confers some form of abuse-deterrence properties when this

¹⁵⁴ ENDO-CHI_LIT-00401875.

has not been demonstrated by substantial evidence.”¹⁵⁵ The FDA acknowledged that while there is “evidence to support some limited improvement” provided by the new coating, but would not let Endo promote any benefit because “there are several limitations to this data.”¹⁵⁶ Also, Endo was required to add language to its label specifically indicating that “Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death.”¹⁵⁷

306. The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012, “request ... for comments on a launch Draft Professional Detail Aid ... for Opana ER.” The FDA’s May 2012 letter also includes a full two pages of comments regarding “Omissions of material facts” that Endo left out of the promotional materials.

307. Endo consciously chose not to do any post-approval studies that might satisfy the FDA. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and “any advantages for commercials will have disappeared.”¹⁵⁸ However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

308. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it

¹⁵⁵ ENDO-CHI_LIT-00075640.

¹⁵⁶ *Id.*

¹⁵⁷ ENDO-CHI_LIT-00075642 (p. 9 of the PDF).

¹⁵⁸ ENDO CHI LIG 65055.

was less able to be crushed and snorted and that it was resistant to injection by syringe.

Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

309. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.¹⁵⁹ The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."¹⁶⁰

310. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."¹⁶¹

¹⁵⁹ Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration*, et al., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

¹⁶⁰ Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration*, et al., No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

¹⁶¹ *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration*, et al., No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

311. In its citizen petition, Endo asserted that redesigned Opana ER had “safety advantages.” Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, “where children unintentionally chew the tablets prior to an accidental ingestion.”¹⁶²

312. However, in rejecting the petition in a 2013 decision, the FDA found that “study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing.” The FDA also determined that “reformulated Opana ER” could also be “readily prepared for injections and more easily injected[.]” In fact, the FDA warned that preliminary data—including in Endo’s own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

313. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had “increased significantly” in the wake of the purportedly abuse-deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, which confirmed continued abuse, particularly by injection.

314. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%. Endo’s own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by

¹⁶² CP, FDA Docket 2012-8-0895, at 2.

injection, compared with 36% for the old formulation.¹⁶³ The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

315. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

316. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that based on the company's detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

317. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential." An internal Endo document also notes that market research showed that, "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of Opana ER

¹⁶³ Theresa Cassidy, et al., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Inflexxion (Sept. 7, 2014) <https://www.inflexxion.com/changing-abuse-ecology-extended-release-oxymorphone/>.

over the next 6 months.”¹⁶⁴

318. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

319. The press release further stated that: “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers. The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

320. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in *Pain Medicine News*, based in part on an Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

321. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Endo targeted particular geographies for the redesigned Opana ER where abuse was most rampant.¹⁶⁵

¹⁶⁴ ENDO-CHI_LIT-00156509 (2008) p.97.

¹⁶⁵ ENDO-CHI_LIT-00054637.

322. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017.¹⁶⁶ Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER.¹⁶⁷ However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

c. Other Marketing Defendants’ misrepresentations regarding abuse deterrence

323. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be abused by health care providers and illicit users” because of its “[s]low onset of action.”¹⁶⁸ Kadian, however, was not approved by the FDA as abuse deterrent, and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Actavis had no studies to suggest it was.

324. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For

¹⁶⁶ Press Release, FDA, FDA requests removal of Opana ER for risks related to abuse, (June 8, 2017), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

¹⁶⁷ Press Release, Endo International plc, Endo Provides Update on Opana ER, (July 6, 2017), available at <https://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html>

¹⁶⁸ ACTAVIS0947868 (09/17/2007) (p. 1-2).

example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."¹⁶⁹ One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."

325. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."¹⁷⁰ In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."¹⁷¹

326. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

327. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by or was contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and

¹⁶⁹ Mallinckrodt Press Release, Medtronic, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>.

¹⁷⁰ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

¹⁷¹ Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, ST. LOUIS BUSINESS JOURNAL (Dec. 30, 2013), <http://argencapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>

elsewhere in this Complaint are misleading and contrary to the Marketing Defendants' products' labels.

B. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

328. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

329. The Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) so-called "key opinion leaders" ("KOLs"), that is, doctors who were paid by the Marketing Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Marketing Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives or "detailers"; and (8) speakers bureaus and programs.

C. The Marketing Defendants Directed Front Groups Deceptively to Promote Opioid Use

330. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.¹⁷² Defendants funded these Front

¹⁷² U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (February 12, 2018), <https://www.hsdl.org/?abstract&did=808171>

Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

331. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”¹⁷³ “Even small organizations—with ‘their large numbers and credibility with policymakers and the public’—have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”¹⁷⁴ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,¹⁷⁵ which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of Office opioids policy,”¹⁷⁶ found that the Marketing Defendants made millions of dollars’ worth of contributions to various Front Groups.¹⁷⁷

332. The Marketing Defendants also “made substantial payments to individual group

(“*Fueling an Epidemic*”), at p. 3

¹⁷³ *Id.* at p. 2.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at p. 1.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at p. 3.

executives, staff members, board members, and advisory board members” affiliated with the Front Groups subject to the Senate Committee’s study.¹⁷⁸

333. As the Senate *Fueling an Epidemic* Report found, the Front Groups “amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain.”¹⁷⁹ They also “lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over prescription and misbranding.”¹⁸⁰

334. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other deceptively to promote the use of opioids for the treatment of chronic pain.

1. American Pain Foundation

335. The most prominent of the Front Groups was APF. While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from

¹⁷⁸ *Id.* at p. 10.

¹⁷⁹ *Id.* at 12-15.

¹⁸⁰ *Id.* at 12.

2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

336. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed supra.

337. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

338. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "*Partners Against Pain*" and Janssen's "*Let's Talk Pain*." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As

Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share its business interests.

339. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

340. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason.

341. APF's Board of Directors was largely comprised of doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's lack of independence in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions.

342. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of

opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

2. American Academy of Pain Medicine and the American Pain Society

343. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.¹⁸¹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

344. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

345. Fishman, who also served as a KOL for Marketing Defendants, stated that he

¹⁸¹ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), available at <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf> (last accessed April 28, 2018).

would place the organization “at the forefront” of teaching that “the risks of addiction are . . . small and can be managed.”¹⁸²

346. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

347. More specifically, Purdue paid \$725,584.95 from 2012-2017 to AAPM.¹⁸³ Janssen paid \$83,975 from 2012-2017 to AAPM.¹⁸⁴ Insys paid \$57,750 from 2012-2017 to AAPM.¹⁸⁵ Endo funded AAPM CMEs. Teva is on AAPM’s corporate relations council.

348. As to APS, Purdue paid \$542,259.52 from 2012-2017.¹⁸⁶ Janssen paid \$88,500 from 2012-2017.¹⁸⁷ Insys paid \$22,965 from 2012-2017.¹⁸⁸ Mylan paid \$20,250 from 2012-2017.¹⁸⁹

¹⁸² Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

¹⁸³ *Id.*

¹⁸⁴ *Fueling an Epidemic Part Two*.

¹⁸⁵ *Id.*

¹⁸⁶ *Fueling an Epidemic Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, <https://www.hsdl.org/?abstract&did=808171> (last accessed April 17, 2018) (hereinafter referred to as “*Fueling an Epidemic Part Two*”)

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

349. AAPM describes its annual meeting as an “exclusive venue” for offering Continuing Medical Education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

350. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

351. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and claimed that the risk of a patients’ addiction to opioids was low. Dr. David Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011.

352. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

353. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College’s Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them

as “skewed” by drug companies and “biased in many important respects,” including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

354. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines.

355. For that reason, the CDC has recognized that treatment guidelines can “change prescribing practices.”¹⁹⁰

356. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

357. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS 2009 Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

¹⁹⁰ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, (March 15, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>, (hereinafter “2016 CDC Guideline”).

3. FSMB

358. The Federation of State Medical Boards (FSMB) is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

359. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

360. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

361. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Palm Beach County.

362. FSMB’s 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. Purdue paid \$100,000 for printing and distribution of FSMB’s Guidelines.¹⁹¹

¹⁹¹ John Fauber, *Follow the Money: Pain, Policy, and Profit*, MILWAUKEE JOURNAL SENTINEL/MEDPAGE TODAY (Feb. 19, 2012), <https://www.medpagetoday.com/neurology/painmanagement/31256>.

363. The publication also received support from the American Pain Foundation (APF) and the American Academy of Pain Medicine (AAPM). The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors), of which 9,100 were distributed in Florida.¹⁹² The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.¹⁹³

364. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

365. Dr. Fishman said that he did not receive any payments from FSMB or any royalties from the publisher because he wanted to avoid the perception of a potential conflict of

¹⁹² Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

¹⁹³ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide* 8-9 (Waterford Life Sciences 2007).

interest in his authorship of the book or for the ongoing efforts of FSMB – this is because prior to 2011, he had been scrutinized for his involvement with the front groups/manufacturers and accepting payments.¹⁹⁴

366. The Manufacturing Defendants made additional contributions to the FSMB to further their misleading advertising. For example, Purdue paid FSMB \$822,400.06 over 8 years.¹⁹⁵ Cephalon paid FSMB \$180,000 over 3 year period 2007-2008 and 2011.¹⁹⁶ Endo paid FSMB \$371,620 over 5 year period.¹⁹⁷ Mallinckrodt paid FSMB \$100,000 in 2011.¹⁹⁸

4. The Alliance for Patient Access

367. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.”¹⁹⁹ It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.²⁰⁰ As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.”

¹⁹⁴ Email from Dr. Scott Fishman to Charles Ornstein, ProPublica (Dec. 15, 2011), <https://assets.documentcloud.org/documents/279033/fishman-responses-to-propublica.pdf>.

¹⁹⁵ Letter from Humayun J. Chaudhry, President and CEO, FSMB, to the Hon. Max Baucus and Hon. Charles Grassley, U.S. Senate (June 8, 2012), <https://www.documentcloud.org/documents/3109089-FSMB-Response-Letter-to-US-Senate.html>.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ The Alliance for Patient Access, *About AfPA*, <http://allianceforpatientaccess.org/about-afpa/#membership> (last accessed April 28, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

²⁰⁰ Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017),

The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

368. APA's board members have also directly received substantial funding from pharmaceutical companies.²⁰¹ For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.²⁰² Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

369. Among its activities, APA issued a "white paper" titled "Prescription Pain

<https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/> ("Jaklevic, *Non-profit Alliance for Patient Access*").

²⁰¹ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at <https://projects.propublica.org/docdollars/>.

²⁰² Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, KANSAS CITY STAR (July 19, 2017), <http://www.kansascity.com/news/business/health-care/article162569383.html>.

Medication: Preserving Patient Access While Curbing Abuse.”²⁰³ Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.²⁰⁴

370. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for

²⁰³ Institute for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

²⁰⁴ *Id.* at 4-5 (footnote omitted).

annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.²⁰⁵

371. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.²⁰⁶

372. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”²⁰⁷

373. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they were generally given to members of

²⁰⁵ *Id.* at 5-6.

²⁰⁶ *Id.* at 6.

²⁰⁷ *Id.* at 7.

Congress who supported the APA's agenda.²⁰⁸

374. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. ("CSA" or "Controlled Substances Act").²⁰⁹ The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"²¹⁰ and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts.²¹¹ The law passed both houses of Congress and was signed into law in 2016.

5. The U.S. Pain Foundation

375. The U.S. Pain Foundation (USPF) was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly \$3

²⁰⁸ Jaklevic, *Non-profit Alliance for Patient Access*, supra n. 200.

²⁰⁹ Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015).

²¹⁰ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (last updated Oct. 17, 2017) <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").

²¹¹ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marquette L. Rev. (forthcoming Feb. 2018), <https://www.documentcloud.org/documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html>.

million in payments between 2012 and 2015 alone.²¹² The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertised its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.²¹³ Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

376. More specifically, Purdue paid \$359,300 from 2012-2017 to the USPF.²¹⁴ Janssen paid \$41,500 from 2012-2017.²¹⁵ Insys paid \$2,500,000 from 2012-2017.²¹⁶

6. American Geriatrics Society

377. The AGS was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The AGS was a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS

²¹² Fueling an Epidemic, at p. 4.

²¹³ *Id.* at 12; U.S. Pain Foundation, *Transparency*, <https://uspainfoundation.org/transparency/>. (last accessed on April 29, 2018).

²¹³ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on April 28, 2018).

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons,²¹⁷ hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.²¹⁸ AGS’s complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive up front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

378. More specifically, Purdue paid \$11,785 from 2012-2017²¹⁹ and provided \$40,000 in “corporate roundtable dues” to AGS’s Health in Aging Foundation, a 501(c)(3) organization affiliated with the group between 2012 and 2015.²²⁰

379. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.²²¹ These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 500 times in

²¹⁷ *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331 (2009), <https://www.ncbi.nlm.nih.gov/pubmed/19573219> (last accessed on April 28, 2018).

²¹⁸ John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

²¹⁹ *Fueling an Epidemic Part Two*.

²²⁰ Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

²²¹ 2009 AGS Guidelines, at 1342.

Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

380. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

381. Dr. Bruce Farrell was a AGS task force chairman for the 2009 Guidelines, but was also a paid speaker for Endo, and he helped conduct a CME for treating osteoarthritis pain, which was funded by Purdue.²²²

382. Representatives of the Marketing Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

383. Members of AGS Board of Directors were doctors who were on the Marketing Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

7. American Chronic Pain Association

384. The Manufacturer Defendants also made substantial payments to the American Chronic Pain Association ("ACPA"). Founded in 1980, the ACPA offers support and education for people suffering with chronic pain.

²²² John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL (May 30, 2012), <https://www.medpagetoday.com/geriatrics/painmanagement/32967>.

385. Contributions to the ACPA from the Manufacturing Defendants include: Purdue paid \$312,470 from 2012-2017.²²³ Janssen paid \$50,000 from 2012-2017.²²⁴ Between 2013 and 2016, 10 members of ACPA's Advisory Board received more than \$140,000 from opioid manufacturers, including Endo.²²⁵

D. The Marketing Defendants Paid Key Opinion Leaders Deceptively to Promote Opioid Use

386. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine and Dr. Scott Fishman.

387. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

388. As the Marketing Defendants' false marketing scheme picked up steam, these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on

²²³ *Fueling an Epidemic Part Two*.

²²⁴ *Id.*

²²⁵ Pulled from Sterling's memo re Endo.

committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

389. Through use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Marketing Defendants were able to exert control of each of these modalities through which doctors receive their information.

390. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

391. The Marketing Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Marketing Defendants' agenda. The Marketing Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Marketing Defendants kept these KOLs well-funded to enable them to push the Marketing Defendants' deceptive message out to the medical community.

392. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the

medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

393. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

1. Dr. Russell Portenoy

394. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."²²⁶

395. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic

²²⁶ Russell Portenoy & Kathy Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

*effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*²²⁷

(emphasis added.) According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”²²⁸

396. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”²²⁹

397. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”²³⁰

398. Dr. Portenoy was also a critical component of the Marketing Defendants’ control

²²⁷ Russell Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

²²⁸ *Id.*

²²⁹ Dreamland at 314.

²³⁰ *Id.* at 136.

over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

399. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.²³¹ Dr. Portenoy has now admitted that he minimized the risks of opioids,²³² and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."²³³ He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."²³⁴

400. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*²³⁵

²³¹ See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

²³² Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (Nov. 8, 2013), <https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic> (hereinafter "Gounder, *Who Is Responsible*").

²³³ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

²³⁴ *Id.*

²³⁵ Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid->

401. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to have always to live with that one.”²³⁶

2. Dr. Lynn Webster

402. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo’s special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

403. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s Opioid Risk Tool (“ORT”) appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient’s Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and

[epidemic-2016-5](#); Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

²³⁶ *Pain Killer*, supra n. 34, at 277.

patient agreements to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors at West Boca Medical Center.

404. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants’ promotional messages, Dr. Webster apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

405. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, “Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively amounted to off-label promotion of Cephalon’s opioids, even though they were approved only for cancer pain.

406. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

3. Dr. Perry Fine

407. Dr. Perry Fine’s ties to the Marketing Defendants have been well documented. He

has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.²³⁷

408. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

409. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s website states that the company paid him \$32,017 for consulting, promotional talks, meals and travel that year.²³⁸

410. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and

²³⁷ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

²³⁸ Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

addiction:

At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.²³⁹

411. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”²⁴⁰ In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for non-cancer pain.”²⁴¹ The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms

²³⁹ Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

²⁴⁰ Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

²⁴¹ *Id.*

of opioid therapy for chronic pain.”²⁴²

412. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”²⁴³

413. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.²⁴⁴ He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.”²⁴⁵ The entire program assumes that opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”²⁴⁶

4. Dr. Scott Fishman

414. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion.

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ Perry A. Fine, M.D., *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), <https://www.youtube.com/watch?v=G3II9yqgXI>

²⁴⁵ *Id.*

²⁴⁶ *Id.*

He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”²⁴⁷

415. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

416. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.²⁴⁸

²⁴⁷ Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry> (hereinafter “Weber, *Two Leaders in Pain*”).

²⁴⁸ Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

417. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.”²⁴⁹

418. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.”²⁵⁰ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

E. The Marketing Defendants Also Spread Their Misleading Messages to Reputable Organizations

419. The Manufacturing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (“The Joint Commission”) in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation’s oldest and largest standards-setting and accrediting body in health care.²⁵¹ Only hospitals that have been accredited by the Joint Commission can receive payments from Medicare and Medicaid.²⁵²

420. In 2000, Purdue sponsored a book through The Joint Commission which

²⁴⁹ *Id.*

²⁵⁰ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

²⁵¹ Joint Commission, *FAQ Page*, available at <https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274> (last accessed April 12, 2018).

²⁵² U.S. S. Comm. on Homeland Security and Government Affairs Field Hearing, “Border Security and America’s Heroin Epidemic: The Impact of the Trafficking and Abuse of Heroin and Prescription Opioids in Wisconsin,” at 6 (Apr. 15, 2016) (Testimony of Time Westlake, M.D., Vice Chairman, State of Wisconsin Medical Examining Board Controlled Substances Committee Chairman) (“Westlake testimony”).

claimed “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”²⁵³ It also called doctors’ concerns about addiction side effects “inaccurate and exaggerated.”²⁵⁴ Dr. David W. Baker, The Joint Commission’s executive vice president for health care quality evaluation, has acknowledged that “The Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information.”²⁵⁵

421. In 2001, due to the influence of the Marketing Defendants, The Joint Commission, along with the National Pharmaceutical Council (founded in 1953 and supported by the nation’s major research-based biopharmaceutical companies²⁵⁶) “introduced standards for [hospitals] to improve their care for patients with pain.” The new standards for hospitals put patient pain front and center as the “fifth vital sign.” This monograph, entitled “Pain: Current understanding of assessment, management and treatments” required assessment of pain in all patients.

422. The Joint Commission’s first pain management standards placed responsibility for pain control on health care organizations (hospitals); and, emphasized the need for hospitals to do systematic assessments and use quantitative measures of pain which was consistent with the position of the Front Group APS.

423. As a result of the Marketing Defendants’ efforts to manipulate the standard of

²⁵³ Sonia Moghe, *Opioid history: From ‘wonder drug’ to abuse epidemic*, CNN (Oct. 13, 2016), <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>.

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ Currently funded by Johnson & Johnson, Purdue and Teva, among others.

care, many hospitals, including Plaintiff, risked loss of their Joint Commission accreditation if they did not incorporate the “fifth vital sign” standard and put pain at the forefront of their treatment. For example, the emergency department at Oconomowoc Memorial Hospital in Wisconsin achieved 10 consecutive years of patient satisfaction in the 99th percentile, a feat no other emergency hospital in the United States has been able to accomplish.²⁵⁷ However, during its routine Joint Commission survey, The Joint Commission found that the hospital was not adequately documenting follow up questions after prescribing pain medications to patients.²⁵⁸ As a result, the hospital was given only one quarter to bring their compliance up to 90%.²⁵⁹ They could not, and as a result their Joint Commission accreditation was at risk for the entire hospital.²⁶⁰ Loss of accreditation by The Joint Commission can result in the loss of a huge amount of hospital resources to become reaccruited, despite having a patient satisfaction rating of 99% for the same period.²⁶¹

424. Since 2001, The Joint Commission standards relating to pain assessment and management have been revised to lessen emphasis on pain. However, the damage caused by the Marketing Defendants’ marketing campaigns could not be undone. Dr. Baker explains that “the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later.”

²⁵⁷ Westlake testimony, at 6.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

F. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

425. Now that the Marketing Defendants had both a group of physician promoters and had built a false body of “literature,” Defendants needed to make sure their false marketing message was widely distributed.

426. One way the Marketing Defendants aggressively distributed their false message was through countless of CME programs.

427. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are generally delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

428. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants’ deceptions.

429. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments,

inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

430. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians across the country.

431. Another Cephalon-sponsored CME presentation titled Breakthrough Pain: Treatment Rationale with Opioids was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis.” He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway.”²⁶² The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.²⁶³ Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

432. Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

433. Responsible Opioid Prescribing was sponsored by Purdue, Endo and Teva. The

²⁶² Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <http://www.medscape.org/viewarticle/461612> (last accessed Oct. 10, 2017).

²⁶³ *Id.*

FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of Responsible Opioid Prescribing with a special introductory letter from Dr. Scott Fishman.

434. In all, more than 163,000 copies of Responsible Opioid Prescribing were distributed nationally.

435. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs create; stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urged that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”²⁶⁴

436. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

437. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants expected and understood that instructors would deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Marketing Defendants both measure the effects of CMEs on prescribers’ views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in

²⁶⁴ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011).

supporting them.

G. The Marketing Defendants Used “Branded” Advertising to Promote their Products to Doctors and Consumers

438. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. The Marketing Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

439. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.²⁶⁵ They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.²⁶⁶ Endo’s research, for example, also found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials in the form of pamphlets, videos, or other publications that patients could view in their physician’s office.

²⁶⁵ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

²⁶⁶ *Id.*

H. The Marketing Defendants Used “Unbranded” Advertising To Promote Opioid Use For Chronic Pain Without FDA Review

440. The Marketing Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s “branded” advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

441. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

I. The Marketing Defendants Funded, Edited And Distributed Publications That Supported Their Misrepresentations

442. The Marketing Defendants created a body of false, misleading, and unsupported

medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

443. To accomplish their goal, the Marketing Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

444. The Marketing Defendants’ plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Marketing Defendants’ marketing departments.

445. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

446. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

447. For example, in 2007 Cephalon sponsored the publication of an article titled “Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Non-cancer Pain:

Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,”²⁶⁷ published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article’s authors (including Dr. Lynn Webster, discussed above) stated that the “OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or ‘short acting’ opioids” and that “[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.²⁶⁸

J. The Marketing Defendants Used “Detailers” To Directly Disseminate Their Misrepresentations To Prescribers

448. The Marketing Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors and hospitals with centrally orchestrated messages. The Marketing Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive.

449. Each Marketing Defendant promoted opioids through sales representatives (also

²⁶⁷ Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Non-cancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) *Pain Med.* 281-88 (Mar. 2007).

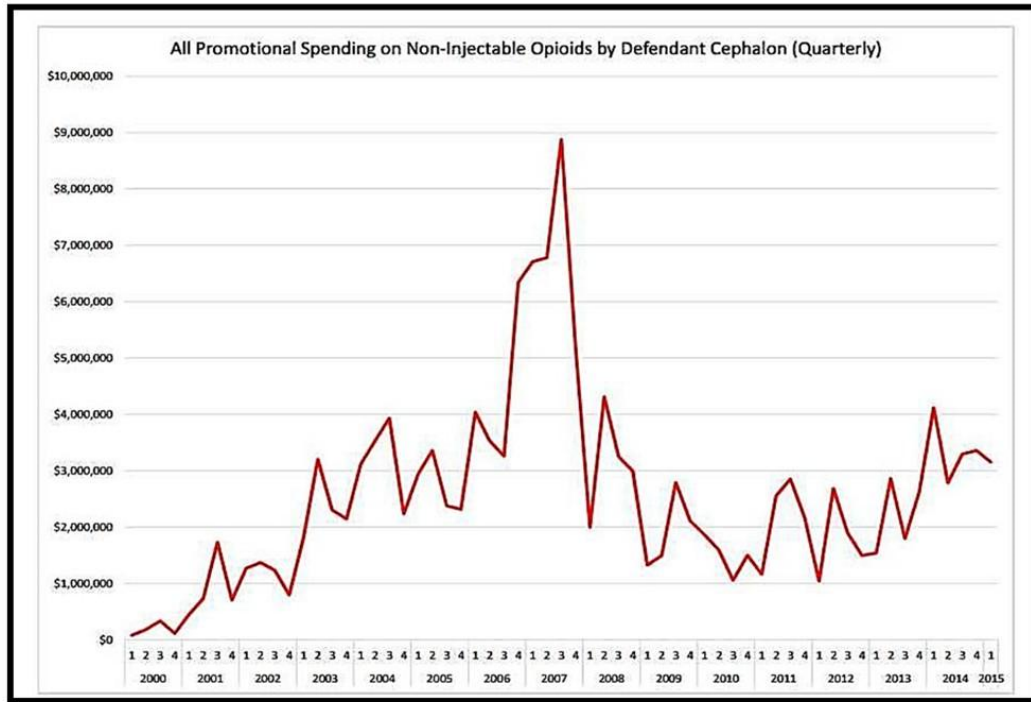
²⁶⁸ *Id.*

called “detailers”) and, in consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

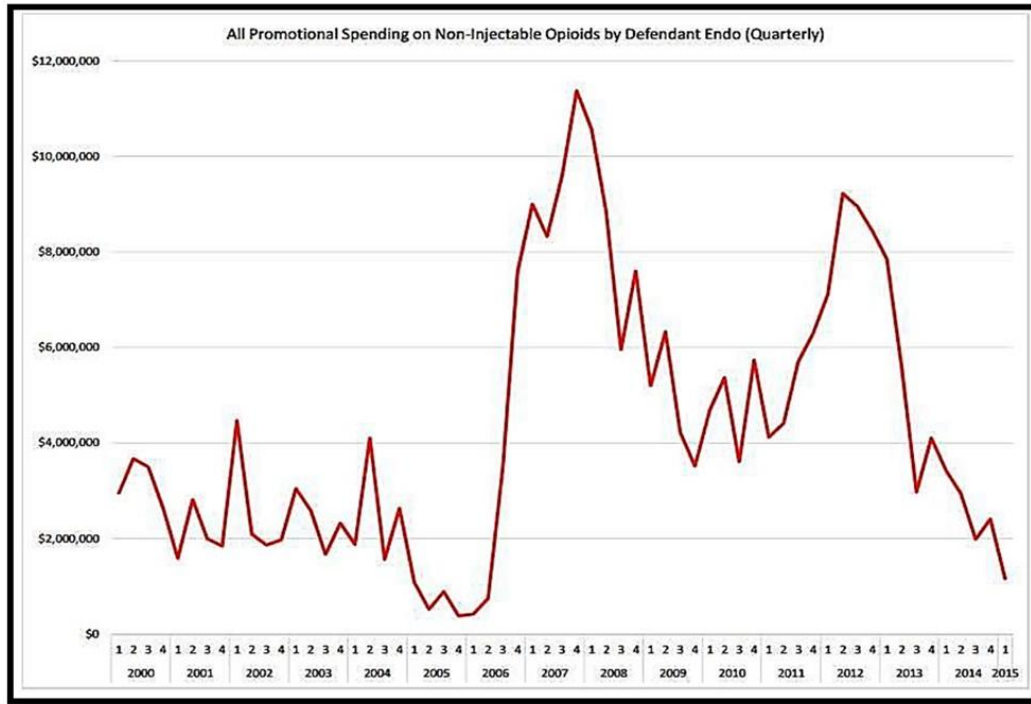
450. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

451. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

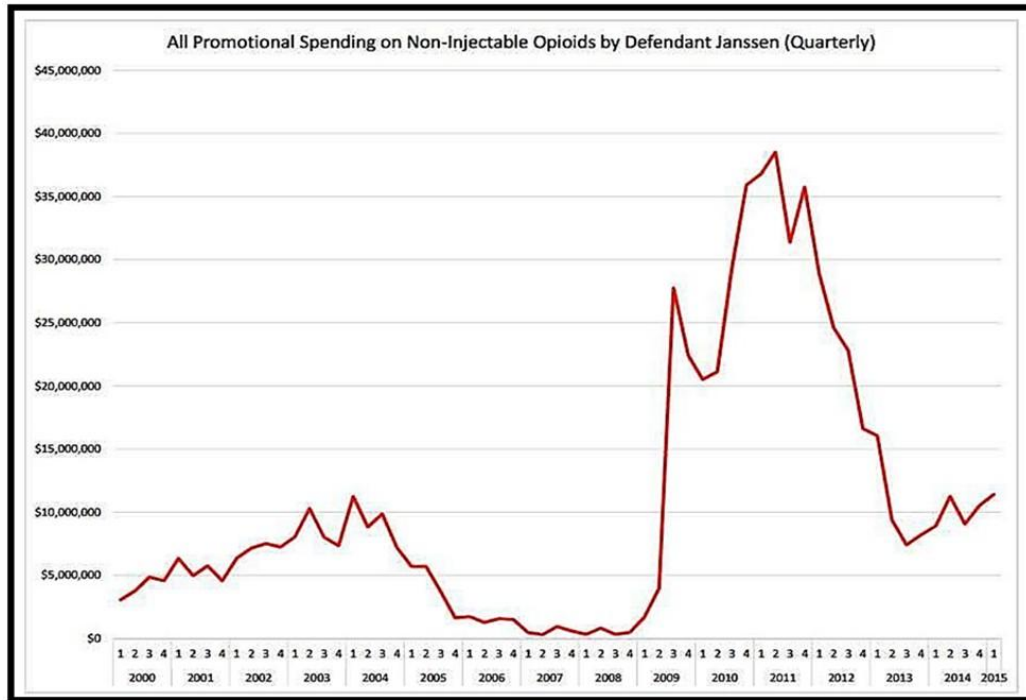
452. Cephalon’s quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:



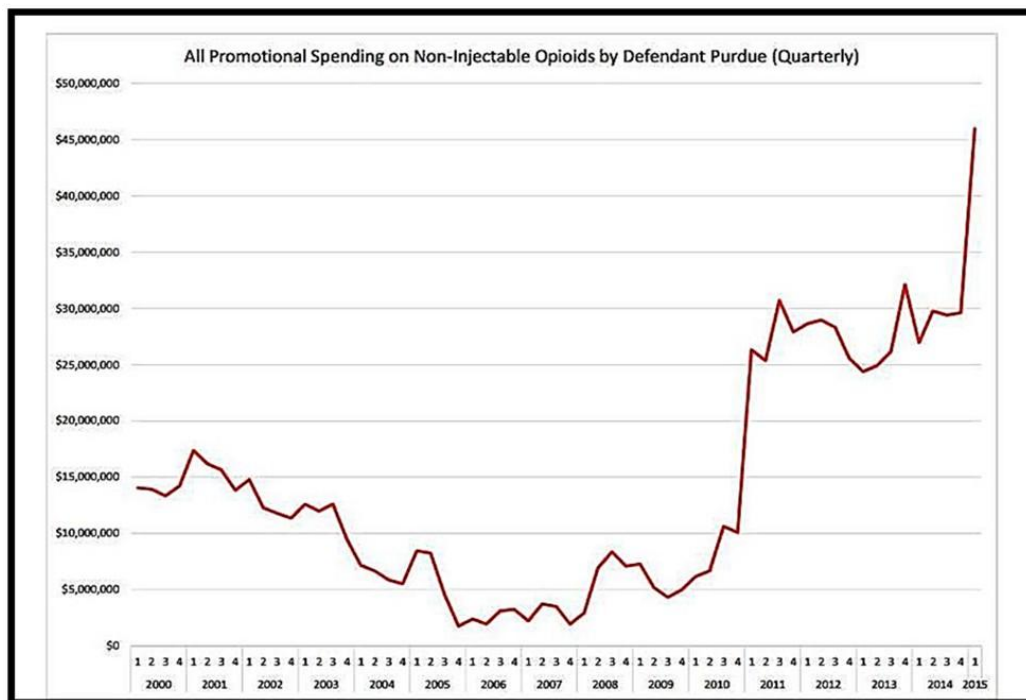
453. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38 million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



454. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



455. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



456. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

457. Thousands of prescribers attended Cephalon speaking programs. Cephalon tracked the impact that these programs had on prescribing in the three months following the event and concluded that doctors' prescribing of Fentora often increased.²⁶⁹

K. The Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

458. In addition to making sales calls, Marketers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

459. As detailed below, Insys paid prescribers for *fake* speakers programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales

²⁶⁹ TEVA_CHI_00001692

representative. It was a pay-to-prescribe program. Insys used speakers programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

L. The Marketing Defendants Targeted Vulnerable Populations

460. The Marketing Defendants specifically targeted their marketing at two particularly vulnerable populations—the elderly and veterans.

461. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

462. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare part D patients among the “most valuable customer segments.”²⁷⁰ However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: “[f]or patients 65 and older these medications are not safe, so consult your doctor.”

463. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

464. Yet the Marketing Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and

²⁷⁰ ENDO-CHI_LIT-00050369; ENDO-CHI_LIT-00076029

distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain medications” while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

465. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

M. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

466. Insys’s opioid, Subsys, was approved by the FDA in 2012 for “management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl (“TIRF”).

467. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a REMS for Subsys and other TIRF products, such as Cephalon’s Actiq and Fentora. The purpose of REMS was to educate “prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose” for this type of drug and to “ensure safe use and access to these

drugs for patients who need them.”²⁷¹ Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

468. Since its launch, Subsys has been an extremely expensive medication, has increased its prices every year. Depending on a patient’s dosage and frequency of use, a month’s supply of Subsys could cost in the thousands of dollars.

469. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report (“Staff Report”), the prior authorization process includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied”²⁷²

470. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading

²⁷¹ Press Release, FDA, *FDA Approves Shared System REMS for TIRF Products*, Dec. 29, 2011.

²⁷² U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (Sept. 6, 2017), <https://www.hsdl.org/?view&did=803959>.

information to insurers and payors regarding patients' diagnoses and medical conditions.

471. Subsys has proved to be extremely profitable for Insys. Insys made approximately \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

472. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

473. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.²⁷³

474. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that

²⁷³ *Id.*

doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks.”²⁷⁴ It was a pay-to-prescribe program.

475. Insys’s sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

476. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

477. In June of 2015, a nurse practitioner in Connecticut described as the state’s highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

²⁷⁴ Roddy Boyd, *Insys Therapeutics and the New “Killing It”*, Southern Investigative Reporting Foundation, THE INVESTIGATOR (April 24, 2015), <http://sirf-online.org/2015/04/24/the-new-killing-it/>.

478. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

479. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an “honorarium” ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the “speaker” being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

480. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys’s founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: “Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis.”²⁷⁵ The DEA Special Agent

²⁷⁵ Press Release, DOJ, U.S. Attorney’s Office, Dist. of Mass., *Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering* (Oct. 26, 2017), available at

in Charge further explained that: “Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers’ health and safety and, indeed, very lives depend on it.”²⁷⁶

VI. THE MARKETING DEFENDANTS’ SCHEME SUCCEEDED, CREATING A PUBLIC HEALTH EPIDEMIC

A. The Marketing Defendants’ Dramatically Expanded Opioid Prescribing and Use

481. The Marketing Defendants necessarily expected a return on the enormous investment they made, in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

482. Endo, for example directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER’s uses; virtually all of Endo’s opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales.

<https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering>.

²⁷⁶ *Id.*

483. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.”²⁷⁷ Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million.²⁷⁸ Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”²⁷⁹

484. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing of their drugs. Their purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors’ prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants’

²⁷⁷ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

²⁷⁸ Carreyrou, *Narcotic Lollipop*.

²⁷⁹ *Id.*

opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, lead them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

485. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.²⁸⁰ The effects of sales calls on prescribers' behavior is well documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

486. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were

²⁸⁰ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

comfortable using opioids for chronic non-cancer pain.²⁸¹ These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

487. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

B. The Marketing Defendants' Deception In Expanding Their Market Created And Fueled The Opioid Epidemic.

488. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."²⁸² It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

489. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."²⁸³

490. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these

²⁸¹ CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, <https://www.ncbi.nlm.nih.gov/pubmed/25485657>.

²⁸² Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, <https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of%20Opioid%20Analgesics.pdf>.

²⁸³ See Califf et al., supra n. 11.

reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

VII. THE MARKETING DEFENDANTS’ MARKETING SCHEME MISREPRESENTED THE RISKS AND BENEFITS OF OPIOIDS

A. The Marketing Defendants Embarked Upon A Campaign Of False, Deceptive, And Unfair Assurances Grossly Understating And Misstating The Dangerous Addiction Risks Of The Opioid Drugs.

491. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Marketing Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Marketing Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

492. To this end, one of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction.” KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.²⁸⁴ The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.²⁸⁵
- b. Janssen sponsored, funded, and edited the Let’s Talk Pain website, in 2009 in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing. Janssen financed and orchestrated the participation of these groups in the website and exercised

²⁸⁴ Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

²⁸⁵ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

substantial control over the content of the website. As a 2009 Janssen memo conceded, “[t]he Let’s Talk Pain Coalition is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.” and “[t]he Coalition and Pricara maintain editorial control of all Let’s Talk Pain materials and publications. According to the Let’s Talk Pain website: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”

- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated.”

493. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse.” In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.

B. The Marketing Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations

494. As a part of their deceptive marketing scheme, the Marketing Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States. For example, the Marketing Defendants focused their deceptive marketing on primary

care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Marketing Defendants' misrepresentations.

495. "From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns."²⁸⁶

496. The Marketing Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Marketing Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.²⁸⁷ The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.²⁸⁸ The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-

²⁸⁶ Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. Journal of Public Health 2 (February 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

²⁸⁷ 2016 CDC Guideline, *supra* n. 190.

²⁸⁸ *Id.* at 27.

traumatic stress disorder, which interact dangerously with opioids.

VIII. THE MARKETING DEFENDANTS MADE MATERIALLY DECEPTIVE STATEMENTS AND CONCEALED MATERIAL FACTS

497. As alleged herein, the Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

A. Purdue

498. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-

dependent risks of opioids versus NSAIDs;

- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

- q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

499. More specifically, Defendant Purdue made and/or disseminated deceptive statements, and promoted a culture that mislead doctors and patients into believing opioids were safe for chronic care, including, but not limited to, the following:

- a. In 1998, Purdue distributed 15,000 copies of an OxyContin video to physicians without submitting it to the FDA for review, an oversight later acknowledged by Purdue. In 2001, Purdue submitted to the FDA a second version of the video, which the FDA did not review until October 2002—after the General Accounting Office inquired about its content. After its review, the FDA concluded that the video minimized the risks from OxyContin and made unsubstantiated claims regarding its benefits to patients.²⁸⁹
- b. According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that “fewer than one per cent” of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)²⁹⁰
- c. Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He told [reporters] that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. “If you look at the prescribing trends for all the different opioids, it’s in 1996 that prescribing really takes off,” Kolodny said. “It’s not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the

²⁸⁹ Patrick R. Keefe, *The Family that Built an Empire of Pain*, THE NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

²⁹⁰ *Id.*

risks.”²⁹¹

- d. “Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: internal Purdue records indicate that doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn’t. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity: the company convinced doctors of the drug’s safety with literature that had been produced by doctors who were paid, or funded, by the company.”²⁹²
- e. Purdue encouraged sales representatives to increase sales of OxyContin through a lucrative bonus system, which resulted in a large number of visits to physicians with high rates of opioid prescriptions. In 2001, Purdue paid \$40 million in bonuses to its sales representatives.²⁹³
- f. Purdue claimed that the risk of addiction from OxyContin was extremely small and trained its sales representatives to carry the message that the risk of addiction was “less than one percent,” while knowing that there was no empirical support for that statement.
- g. By 2003, the Drug Enforcement Administration had found that Purdue’s “aggressive methods” had “very much exacerbated OxyContin’s widespread abuse.” Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had “deliberately minimized” the risks associated with the drug.²⁹⁴

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

²⁹⁴ *The Family that Built an Empire of Pain*, <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>

500. As noted above, Purdue utilized Front Groups to help disseminate and defend its false messages. Between January 2012 and March 2017, Purdue made the following contributions:

Academy of Integrative Pain Management	\$1,091,024.86
American Academy of Pain Management	\$725,584.95
ACS Cancer Action Network	\$168,500.00 ²⁹⁵
American Chronic Pain Association	\$312,470.00
American Geriatrics Society	\$11,785.00 ²⁹⁶
American Pain Foundation	\$25,000
American Pain Society	\$542,259.52
American Society of Pain Educators	\$30,000
American Society of Pain Management Nursing	\$242,535.00
The Center for Practical Bioethics	\$145,095.00
U.S. Pain Foundation	\$359,300.00
Washington Legal Foundation	\$500,000.00
TOTAL	\$4,153,554.33

B. Endo

501. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-

²⁹⁵ Payments from Purdue to the American Cancer Society Cancer Action Network include payments to the American Cancer Society that could potentially have applied to the Cancer Action Network. Production from Purdue Pharma to the Senate Homeland Security and Governmental Affairs Committee (Nov. 13, 2017).

²⁹⁶ The AGS reported that Purdue also provided \$40,000 in “corporate roundtable dues” to its AGS Health in Aging Foundation, a 501(c)(3) organization affiliated with the group, between 2012 and 2015. Letter from Nancy E. Lundebjerg, Chief Executive Office, American Geriatrics Society, to Sen. Claire McCaskill (Oct. 11, 2017).

term for the treatment of chronic non-cancer pain;

- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations – including over \$5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- l. Directly distributing and assisting in the dissemination of literature

written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing.

C. Janssen

502. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made

deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

D. Cephalon

503. Defendant Cephalon made and/or disseminated untrue, false and deceptive

statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

E. Actavis

504. Defendant Actavis made and/or disseminated deceptive statements, and

concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

IX. MARKETING DEFENDANTS PRIOR BAD ACTS

505. Defendants have long known about the dangers of their opioid products, and the alarming quantities in which they were pouring into communities all across the country, because they have been sued, fined, and criminally convicted for failing to mitigate these problems.

506. For example, in 2007 Purdue settled criminal and civil charges against it for “misbranding” OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly \$635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin’s risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.²⁹⁷

²⁹⁷ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

507. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana,²⁹⁸ the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA required “that Endo Pharmaceuticals remove [Opana ER] from the market.” The agency sought removal “based on its concern that the benefits of the drug may no longer outweigh its risks.”²⁹⁹

508. In 2017, The Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.

X. THE DISTRIBUTOR DEFENDANTS’ UNLAWFUL DISTRIBUTION OF OPIOIDS

509. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.11, 21CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

510. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

511. Each Distributor Defendant repeatedly and purposefully breached its duties

²⁹⁸ Press Release, State of Ind. Health Dep’t, HIV Outbreak in Southeastern Indiana, (February 25, 2015), http://www.in.gov/activecalendar/EventList.aspx?fromdate=1/1/2015&todate=12/31/2015&display=Month&type=public&eventidn=210259&view=EventDetails&information_id=211489.

²⁹⁹ Jen Christensen, *FDA wants Opioid Painkiller Pulled off Market*, CNN (June 8, 2017), <https://www.cnn.com/2017/06/08/health/fda-opioid-opana-er-bn/index.html>; Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

512. For over a decade, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

513. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

514. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

XI. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

515. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

516. Defendants are all required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

517. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants' deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent (“MME”) per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

518. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”³⁰⁰ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”³⁰¹

³⁰⁰ CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., et al., “Increases in drug and opioid overdose deaths—United States, 2000–2014.” *American Journal of Transplantation* 16.4 (2016): 1323-1327.

³⁰¹ *Id.*

A. All Defendants Have a Duty to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders

519. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Defendants have specific duties under federal law as well. Each Defendant was required to register with the DEA, pursuant to the CSA. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Defendant is a “registrant” of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

520. Each Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that “requirements” of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§ 823(b)(1).

521. Federal regulations impose a non-delegable duty upon requirements to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

522. “Suspicious orders” include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop

over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

523. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.*

524. These prescription drugs are regulated for the purpose of providing a “closed” system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.³⁰²

525. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant’s role

³⁰² *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

and responsibilities.³⁰³

526. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their

³⁰³ Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter Brief for HDMA and NACDS). The Healthcare Distribution Mgmt. Ass'n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, <https://www.healthcaredistribution.org/about> (last accessed April 12, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, ~~Rite Aid~~ Corporation and Walmart. *See generally* NACDS, *Mission*, <https://www.nacds.org/%20about/mission/> (last accessed April 12, 2018).

dispensing customers.

527. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”³⁰⁴

528. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.³⁰⁵

529. The DEA’s September 27, 2006 letter also warned the Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”³⁰⁶ The letter also

³⁰⁴ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter Rannazzisi Letter) (“This letter is being sent to every commercial entity in the United States registered with the Drug Enf’t Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

³⁰⁵ See Brief for HDMA and NACDS, supra n. 303, 2016 WL 1321983, at *4 (“[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”).

³⁰⁶ Rannazzisi Letter, supra note 304, at 2.

instructs that “distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.”³⁰⁷ The DEA warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

530. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.³⁰⁸ This letter reminds the Distributor Defendants of their statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”³⁰⁹ The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant’s DEA Certificate of Registration.³¹⁰

³⁰⁷ *Id.* at 1.

³⁰⁸ *Id.* at 2.

³⁰⁹ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

³¹⁰ *Id.*

531. Finally, the DEA letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”³¹¹

532. The Distributor Defendants admit that they “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”³¹²

533. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.” Mallinckrodt further stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

534. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution

³¹¹ *Id.*

³¹² See Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass’n in Support of App. Cardinal Health, Inc., *Cardinal Health, Inc. v. U.S. Dep’t of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter Brief of HDMA in Support of Cardinal).

Management Association, the trade association of pharmaceutical distributors, explain that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.³¹³

535. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

536. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which the Distributor Defendants knew

³¹³ Healthcare Distribution Mgmt. Ass’n (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

prescription opioids were likely to be diverted.

537. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

538. Each Distributor Defendant owes a duty under federal law to investigate and refuse suspicious orders of prescription opioids.

539. Each Distributor Defendant owes a duty under federal law to report suspicious orders of prescription opioids.

540. Each Distributor Defendant owes a duty under federal law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

541. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by others.

542. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the associated costs associated with the treatment of these conditions and related health consequences caused by opioid abuse.

543. Finding it impossible to legally achieve their ever increasing sales ambitions Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

544. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and

control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12 Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able “to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers.” Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

545. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

546. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the practice as industry-wide, and the Healthcare Distribution Alliance (“HDA”) includes a “Contracts and Chargebacks Working Group,” suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that “[a]s part of their business

model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).” The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants,” meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

547. A dramatic example of the use of IMS information came out in the Congressional testimony:

Mr. Greenwood: Well, why do you want that [IMS] information then?

Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.

Mr. Greenwood. And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent “X” number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?

Mr. Friedman: Sure.³¹⁴

548. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in

³¹⁴ *Oxycontin: Its Use and Abuse: Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives*, 107th Cong. 54 (2001) (statements of James C. Greenwood, Member, Committee on Energy and Commerce and Michael Friedman, Executive Vice President and COO of Purdue Pharma, L.P.), available at <https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm>.

exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

1. PCF

549. PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

550. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”³¹⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.³¹⁶

551. The Defendants who stood to profit from expanded prescription opioid use are

³¹⁵ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic> (emphasis added).

³¹⁶ *Id.*

members of and/or participants in the PCF.³¹⁷ In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.³¹⁸ Each of the Marketing Defendants worked together through the PCF. But, the Marketing Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.³¹⁹ The Distributor Defendants participated directly in the PCF as well.

2. HDA

552. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.³²⁰ Additionally, the HDA and each of the Distributor Defendants, eagerly sought the

³¹⁷ *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>

³¹⁸ *Id.* Mallinckrodt became an active member of the PCF sometime after 2012.

³¹⁹ *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance (last accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/executive-committee%20>.

³²⁰ *Manufacturer Membership*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/about/membership/manufactur> (last accessed on September 14,

active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including “strengthening . . . alliances.”³²¹

553. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”³²² The HDA and the Supply Chain Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturers and Supply Chain Defendants.

554. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.³²³ For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

555. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their “most recent year end net sales” through wholesale

2017).

³²¹ *Manufacturer Membership Benefits*, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>

³²² *Id.*

³²³ *Id.*

distributors, including the Distributor Defendants AmerisourceBergen, Cardinal, and McKesson and their subsidiaries.

556. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

557. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."³²⁴ The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."³²⁵ The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.³²⁶

558. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: "This council, composed of distributor and

³²⁴ *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers> (last accessed on September 14, 2017, and no longer available).

³²⁵ *Id.*

³²⁶ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, <https://www.healthcaredistribution.org/events/2015-distribution-management-conference> (last accessed on September 14, 2017).

manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues.”

- b. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

559. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.³²⁷ For example, on April 27, 2011, the HDA offered a Webinar to “accurately and

³²⁷ *Webinars*, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edl>.

effectively exchange business transactions between distributors and manufacturers...” The Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

560. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

561. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

562. Publications and guidelines issued by the HDA nevertheless confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the Fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

563. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and

Commerce Subcommittee on Health in April 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

564. The Defendants’ scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing Defendants worked together to control the state and federal government’s response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

565. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

566. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high. In so doing, they ensured that suspicious orders were not reported to the DEA, and, further, in so doing, they ensured that the DEA had no basis for either refusing to increase production quotas or decreasing production quotas due to diversion.

567. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other’s compliance with their reporting obligations.

568. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

569. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

570. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

571. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

C. Defendants Kept Careful Track of Prescribing Data and Knew About

Suspicious Orders and Prescribers

572. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

573. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

574. This information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;
- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

575. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

576. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

577. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.³²⁸ The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

³²⁸ *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

578. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.³²⁹

579. IMS, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.³³⁰

580. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.³³¹

581. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.³³² Defendants were, therefore, collectively aware of the suspicious orders that flowed

³²⁹ A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

³³⁰ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p. 3 (last accessed April 28, 2018).

³³¹ *Sorrell v. IMS Health Inc.*, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

³³² In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; see also

from their facilities.

582. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012³³³ and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.³³⁴

583. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

584. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the

Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

³³³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

³³⁴ *Id.*

other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.³³⁵ In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."³³⁶

585. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"³³⁷ She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."³³⁸ This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the

³³⁵ *Pain Killer*, supra n. 34 at 298-300.

³³⁶ *Id.*

³³⁷ Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

³³⁸ *Id.*

clinic was shut down in 2010 to inform the authorities.

586. A Kadian prescriber deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." (p. 1-2). The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.³³⁹

587. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

588. Defendants purchased data from IMS (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

589. For example, at a national sales meeting presentation in 2011, Actavis pressed its

³³⁹ ACTAVIS0947868 (09/17/2007).

sales representatives to focus on its high prescribers: “To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into ‘the big leak’. We need to fill the bucket faster than it leaks.” “The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions.” (pg 13). In an example of how new patients + a high volume physician can impact performance: “102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week.”³⁴⁰

590. The same is true for other Defendants.³⁴¹ Teva directed its sales representatives to make a “minimum of seven Fentora calls per day” and focus “on high prescribers to maintain and grow their contribution.” Another chart showed Cephalon ensured that the majority highest- volume or “core prescribers,” were detailed at least five times in ten months.

591. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

592. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named

³⁴⁰ ACTAVIS0969604.

³⁴¹ TEVA_CH_00002233.

Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”³⁴²

593. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

594. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company’s policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

595. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most

³⁴² *Pain Killer*, supra n. 34 at 179.

egregious examples eventually made the nightly news.

D. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

596. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids in disregard of their legal duties to control the supply, prevent diversion, report and take steps to halt suspicious orders.

597. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

598. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.”

599. McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson

Distribution Centers.” Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which investigators found “were supplying pharmacies that sold to criminal drug rings.”

600. Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”

601. On December 23, 2016, Cardinal agreed to pay the United States \$44 million to resolve allegations that it violated the CSA in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
- b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”;
- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

602. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities demonstrate that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for \$16 million to the state; Cardinal settled for \$20 million.

603. Thus, Defendants have admitted disregarding their duties. They have admitted that they pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

604. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all.

605. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the

DEA, McKesson claimed to have “taken steps to prevent such conduct from occurring in the future,” including specific measures delineated in a “Compliance Addendum” to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

606. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti- diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

607. Along the same lines, Defendant McKesson publicly claims that its “customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process,” creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

608. Defendant AmerisourceBergen, too, has taken the public position that it is “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

609. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Supply Chain Defendants, through their trade associations, HDMA and NACDS, filed an amicus brief in *Masters Pharmaceuticals*, which made the following statements:³⁴³

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

³⁴³ Brief for HDMA and NACDS, *supra* n. 303, 2016 WL 1321983, at *3-4, *25.

610. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Supply Chain Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

611. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . .”

612. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids and its “strong record of coordination with law enforcement.”³⁴⁴

613. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid abuse.

614. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are acutely

³⁴⁴ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label* (May 5, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontin-fda-approved-label/>; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

aware of the public health risks these powerful medications create That’s why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse”³⁴⁵ Purdue’s statement on “Opioids Corporate Responsibility” likewise states that “[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government.”³⁴⁶ And, responding to criticism of Purdue’s failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion.”³⁴⁷

615. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

616. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due

³⁴⁵ Purdue website, *Opioids With Abuse-Deterrent Properties*, available at <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/>.

³⁴⁶ Purdue website, *Opioids With Abuse-Deterrent Properties*, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last accessed April 29, 2018).

³⁴⁷ Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straighton-our-anti-diversion-programs/>. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

F. The Distributor Defendants Breached their Duties

617. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.³⁴⁸

618. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.³⁴⁹

619. The Distributor Defendants failed to report “suspicious orders,” or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

620. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

³⁴⁸ See Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

³⁴⁹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

621. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

622. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

623. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

624. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.³⁵⁰

625. The federal laws at issue here are public safety laws.

626. The Distributor Defendants’ violations of public safety statutes constitute prima facie evidence of negligence under State law.

627. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates.

628. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

³⁵⁰ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

629. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

1. McKesson

630. To date, McKesson has agreed to pay over \$163 million to resolve government charges regarding diversion.

631. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson had failed to maintain effective controls against diversion of controlled substances in Florida, Maryland, Colorado, Texas, Utah, and California (the "2008 McKesson Settlement Agreement").³⁵¹

632. In the 2008 McKesson Settlement Agreement, McKesson agreed to pay a \$13.25 million civil fine for its failure to report suspicious orders from rogue Internet pharmacies around the country that resulted in millions of doses of controlled substances being diverted.³⁵²

633. In the 2008 McKesson Settlement Agreement, McKesson specifically "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA."³⁵³ Specifically, McKesson agreed to "maintain a compliance

³⁵¹ Press Release, U.S. Dep't of Justice, McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications (May 2, 2008) <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

³⁵² *Id.*

³⁵³ *Id.*

program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders . . . and follow the procedures established by its Controlled Substance Monitoring Program.”³⁵⁴ But McKesson failed to do so. It was later revealed that McKesson's system for detecting “suspicious orders” from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders, but reported just 16 orders as suspicious - all from only a single consumer.³⁵⁵

634. In January 2017, McKesson further admitted to its ongoing breach of its duties to monitor, report, and prevent suspicious orders of oxycodone and hydrocodone by entering into a Settlement Agreement and Release with the DEA and the United States Department of Justice (the “2017 Settlement Agreement”).³⁵⁶

635. The 2017 McKesson Settlement Agreement required McKesson to pay a record \$150 million civil penalty for violations of the CSA for its operations in California, Colorado, Florida, Illinois, Massachusetts, Michigan, Missouri, Kentucky, Nebraska, New Jersey, Ohio, Washington, West Virginia, and Wisconsin.³⁵⁷

636. In the 2017 McKesson Settlement Agreement, McKesson admitted that, between January 1, 2009 and January 17, 2017, it “did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the

³⁵⁴ *Id.*

³⁵⁵ Press Release, U.S. Dep’t of Justice, McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017), <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

³⁵⁶ The 2017 Settlement Agreement, *available at*: <https://www.justice.gov/opa/press-release/file/928471/download>.

³⁵⁷ *Id.*

guidance contained in the DEA Letters.”³⁵⁸ Despite its obligations contained in the 2008 Settlement Agreement, McKesson “failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).”³⁵⁹

637. In the 2017 McKesson Settlement Agreement, McKesson further admitted that it had “distributed controlled substances to pharmacies even though those [McKesson] Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a).”³⁶⁰ McKesson admitted that it had “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations.”³⁶¹

638. As part of the 2017 McKesson Settlement Agreement, McKesson agreed that its authority to distribute controlled substances from 12 distribution centers would be partially suspended for several years.³⁶² The overall sanctions included in the 2017 Settlement Agreement were the most severe ever imposed on a DEA-registered distributor.

³⁵⁸ *Id.* at 5.

³⁵⁹ *Id.* at 3.

³⁶⁰ *Id.* at 4.

³⁶¹ *Id.* at 3.

³⁶² *Id.*

2. Cardinal

639. To date, Cardinal has paid a total of \$98 million in fines and other amounts involving multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

640. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses³⁶³ around the United States (the “2008 Cardinal Settlement Agreement”).³⁶⁴ These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.³⁶⁵

641. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that “[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled

³⁶³ Including its Lakeland, Florida facility. <https://www.dea.gov/pubs/pressrel/pr100608.html>. In 2012, Cardinal described the Lakeland facility as shipping “an average of about 4 million dosage units of prescription drugs, including about 500,000 dosage units of controlled substances, on a monthly basis to more than 5,200 customers in Florida, Georgia and South Carolina. The volume of prescription drugs distributed makes the Lakeland facility the largest prescription drug wholesaler in Florida.” *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. 3-1, at 6; 3-13 at 2; 3-15 (Feb. 3, 2012).

³⁶⁴ Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), a cached version is available at https://webcache.googleusercontent.com/search?q=cache:O7Te0HbVfpIJ:https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf+&cd=2&hl=en&ct=clnk&gl=us; Press Release, U.S. Att’y Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay \$34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁶⁵ *Id.*

substances filled by its distribution facilities located throughout the United States.”³⁶⁶ The DEA concluded that “Cardinal’s conduct allowed the ‘diversion’ of millions of dosage units of hydrocodone from legitimate to non-legitimate channels.”³⁶⁷

642. As part of the 2008 Settlement Agreement, Cardinal agreed to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations.”³⁶⁸ Despite the Settlement Agreement, “the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal [failed] to maintain effective controls against diversion.”³⁶⁹ For example, from “2008-2009, Cardinal’s sales to its top four retail pharmacies [in the State of Florida] increased approximately 803%. From 2009 to 2010, Cardinal’s sales to its top four retail pharmacies [in the State of Florida] increased 162%.”³⁷⁰

643. In 2012, Cardinal reached another settlement with the DEA relating to its failure to “conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels” resulting in systemic opioid diversion in its Florida

³⁶⁶ U.S. Att’y Office, Dist. of Colo., *Cardinal Health Inc. Agrees to Pay \$34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

³⁶⁷ *Id.*

³⁶⁸ *Cardinal Health, Inc. v. Eric Holder, Jr., Att’y Gen.*, D.D.C. Case No. 12-185, ECF No. [3-4](#), at ¶ [2](#) (Feb. 3, 2012).

³⁶⁹ *Id.* at ¶ 3.

³⁷⁰ *Id.* at ¶ 4.

distribution center (the “2012 Cardinal Settlement Agreement”).³⁷¹ Cardinal’s Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.³⁷² The DEA found that Cardinal’s own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.³⁷³ Instead, Cardinal’s opioid shipments to the pharmacies increased.³⁷⁴

644. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.³⁷⁵

645. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes, this time for \$44 million (the

³⁷¹ Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed April 12, 2018); Press Release, Drug Enf’t Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor’s Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), <https://www.dea.gov/pubs/pressrel/pr051512.html>.

³⁷² *Id.*

³⁷³ *Id.*

³⁷⁴ *Id.*

³⁷⁵ Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed April 12, 2018).

“2016 Cardinal Settlement Agreement”).³⁷⁶ The settlement covered DEA allegations that Cardinal had failed to report suspicious orders across Washington, Maryland, New York, and Florida.³⁷⁷ The same Florida distribution center at the heart of the 2012 settlement was again implicated in this case.³⁷⁸ The settlement also covered a Cardinal subsidiary, Kinray, LLC, which failed to report a single suspicious order despite shipping oxycodone and hydrocodone to more than 20 New York-area pharmacy locations that placed unusually high orders of controlled substances at an unusually frequent rate.³⁷⁹

3. AmerisourceBergen

646. AmerisourceBergen has paid \$16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

647. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.³⁸⁰ Over the course of one year, AmerisourceBergen had distributed 3.8 million dosage units of hydrocodone to “rogue pharmacies.”³⁸¹ The DEA suspended AmerisourceBergen's registration after determining that “the continued registration of this

³⁷⁶ U.S. Att’y Office, Dist. of Md., *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

³⁷⁷ *Id.*

³⁷⁸ *Id.*

³⁷⁹ *Id.*

³⁸⁰ Press Release, Drug Enf’t Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), <https://www.dea.gov/divisions/mia/2007/mia042407p.html>.

³⁸¹ *Id.*

company constitutes an imminent danger to public health and safety.”³⁸²

648. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.³⁸³

G. The Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties

649. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants’ compliance with their legal duties.

650. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the Healthcare Distribution Management Association, n/k/a HDA, a trade association run the Distributor Defendants, and the National Association of Chain Drug Stores (“NACDS”) submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the “DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled.”³⁸⁴
- b. The Associations argued that, “DEA now appears to have changed its

³⁸² *Id.*

³⁸³ Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion*, Law360.com (Aug. 9, 2012), available at <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion>.

³⁸⁴ Brief for HDMA and NACDS, *supra* n. 303, 2016 WL 1321983, at *4–5.

position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications.”³⁸⁵

- c. The Associations alleged (inaccurately) that nothing “requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious.”³⁸⁶
- d. The Associations complained that the purported “practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties.”³⁸⁷
- e. The Associations alleged (inaccurately) that “DEA’s regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders.”³⁸⁸
- f. Also inaccurately, the Associations argued that, “[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA’s demands.”³⁸⁹

651. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of

³⁸⁵ *Id.* at *8 (citations and quotation marks omitted).

³⁸⁶ *Id.* at *14.

³⁸⁷ *Id.* at *22.

³⁸⁸ *Id.* at *24–25

³⁸⁹ *Id.* at 26.

the dangerous drugs.³⁹⁰

652. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. In *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017), the D.C. Circuit Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

653. Because of the Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.³⁹¹ As noted above, the Office of Administrative Law

³⁹⁰ See Brief of HDMA in Support of Cardinal, *supra* n. 312, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

³⁹¹ Evaluation and Inspections Div., Off. of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* (May 2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.³⁹² These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center (“Orlando Facility”) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Auburn, Washington Distribution Center (“Auburn Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;

³⁹² *Id.*

- g. On September 30, 2008, Cardinal entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Lakeland, Florida Distribution Center (“Lakeland Facility”) for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA.

654. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure”

any violations of law before a suspension order can be issued.³⁹³

655. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

656. For example, a Cardinal executive claimed that it uses “advanced analytics” to monitor its supply chain, and represented that it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”³⁹⁴ Given the sales volumes and the company’s history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

657. Similarly, Defendant McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is

³⁹³ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.2f757833e3c4; Lenny Bernstein & Scott Higham, *Investigations: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASHINGTON POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.7007bf2b9455; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, CHARLESTON GAZETTE-MAIL (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

³⁹⁴ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

“deeply passionate about curbing the opioid epidemic in our country.”³⁹⁵ Again, given McKesson’s historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

658. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts.

659. Meanwhile, the opioid epidemic rages unabated in the United States.

660. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

661. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff’s racketeering allegations below.

662. The Distributor Defendants have abandoned their duties imposed under federal law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances.

³⁹⁵ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, WASHINGTON POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.4a72ad72cc8f.

XII. THE NATIONAL RETAIL PHARMACIES WERE ON NOTICE OF AND CONTRIBUTED TO ILLEGAL DIVERSION OF PRESCRIPTION OPIOIDS

663. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.³⁹⁶ They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

664. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

665. Statewide ARCOS data will confirm that the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Florida. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Florida. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

666. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Florida in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a

³⁹⁶ Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the US.

valuable resource that they could have used to help stop diversion, but failed to do so.

A. The National Retail Pharmacies Have a Duty to Prevent Diversion

667. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

668. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

669. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

670. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

671. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for

antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

672. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

673. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

674. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

675. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew they made money by filling prescriptions, not by not filling prescriptions. They knew they made money by making it easy for doctors to refer patients to them to fill drug prescriptions, not by making it difficult for doctors to refer patients to them to fill prescriptions.

676. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS’s Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for

pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The National Retail Pharmacies had no incentive to stop the outflow, and every financial incentive to further it. Their policies and practices remained in place even as the epidemic raged.

677. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

678. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

679. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies failed to analyze: (a) the number

of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

680. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

681. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

682. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

B. Multiple Enforcement Actions against the National Retail Pharmacies Confirms Their Compliance Failures

683. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. In consideration of a reasonable opportunity for further

investigation and discovery, Plaintiff alleges that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

1. CVS

684. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

685. CVS is a repeat offender; the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

686. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.³⁹⁷

687. This fine was preceded by numerous others throughout the county.

688. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties

³⁹⁷ Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act>.

under the CSA and filling prescriptions with no legitimate medical purpose.³⁹⁸

689. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.³⁹⁹

690. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.⁴⁰⁰

691. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.⁴⁰¹

692. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The

³⁹⁸ Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches \$8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), <https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled>.

³⁹⁹ Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays \$600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), <https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations>.

⁴⁰⁰ Dialynn Dwyer, *CVS will pay \$795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), <https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state>.

⁴⁰¹ Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of Just. (June 30, 2016), <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions>.

United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.⁴⁰²

693. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, “based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”⁴⁰³

694. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.⁴⁰⁴

695. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City

⁴⁰² Press Release, U.S. Attorney’s Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With \$450,000 Civil Settlement, U.S. Dep’t of Just. (Aug. 10, 2015), <https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement>.

⁴⁰³ Press Release, U.S. Attorney’s Office M. Dist. of Fla., United States Reaches \$22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances, U.S. Dep’t of Just. (May 13, 2015), <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution>.

⁴⁰⁴ Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), <http://www.expressnews.com/business/local/article/H-E-B-CVS-fined-over-prescriptions-5736554.php>.

metropolitan area.⁴⁰⁵

696. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.⁴⁰⁶

2. Walgreens

697. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than \$118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

698. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—\$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.⁴⁰⁷

699. As part of the settlement, Walgreens admitted that it failed to uphold its

⁴⁰⁵ Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), <http://newsok.com/article/5415840>.

⁴⁰⁶ Press Release, U.S. Attorney's Office W. Dist. of Okla., *CVS to Pay \$11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act*, U.S. Dep't of Just. (Apr. 3, 2013), <https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled>.

⁴⁰⁷ Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled>.

obligations as a DEA registrant regarding the above-described conduct.⁴⁰⁸

700. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

701. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.⁴⁰⁹

702. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that “if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,” underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.⁴¹⁰

703. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for

⁴⁰⁸ *Id.*

⁴⁰⁹ Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

⁴¹⁰ *Id.*

significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.⁴¹¹

704. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.⁴¹²

705. Walgreens has also settled with a number of state attorneys general, including West Virginia (\$575,000) and Massachusetts (\$200,000).⁴¹³

706. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

707. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite

⁴¹¹ *Id.*

⁴¹² *Id.*

⁴¹³ *Walgreens to pay \$200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay \$200,000 and follow certain procedures for dispensing opioids.⁴¹⁴

3. ~~Rite Aid~~

708. ~~With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third largest in the United States, with annual revenue of more than \$21 billion.~~

709. ~~In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.~~⁴¹⁵

710. ~~The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).~~⁴¹⁶

711. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

⁴¹⁴ *Id.*

⁴¹⁵ ~~Press Release, Dep't of Just., Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, U.S. Dep't of Just. (Jan. 12, 2009), <https://www.justice.gov/opa/pr/rite-aid-corporation-andsubsidiaries-agree-pay-5-million-civil-penalties-resolve-violations>.~~

⁴¹⁶ ~~*Id.*~~

712. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

713. Throughout the country and in Florida in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

714. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Florida and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

715. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

716. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

717. The National Retail Pharmacies’ actions and omissions in failing to effectively

prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

XIII. THE MARKETING DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS

718. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Marketing Defendants under federal law.

719. Like the Distributor Defendants, the Marketing Defendants were required to register with the DEA to manufacture Schedule II controlled substances, like prescription opioids. See 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . .

21 USCA § 823(a)(1) (emphasis added).

720. Additionally, as “registrants” under Section 823, the Marketing Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74; *see also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).”

721. Like the Distributor Defendants, the Manufacture Defendants breached these

duties.

722. The Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Marketing Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Marketing Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

723. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

724. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.⁴¹⁷

⁴¹⁷ See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July

725. In the press release accompanying the settlement, the Department of Justice stated: “[Mallinckrodt] did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere.” . . . “Mallinckrodt’s actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street.” . . . “Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . .”⁴¹⁸

726. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”⁴¹⁹

727. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor

11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

⁴¹⁸ *Id.*

⁴¹⁹ *Id.*

these sales and report suspicious orders to DEA.”⁴²⁰

728. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

- a. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to: conduct adequate due diligence of its customers;
- b. detect and report to the DEA orders of unusual size and frequency;
- c. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
 - i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
 - ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
 - iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
- d. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

⁴²⁰ Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (“2017 Mallinckrodt MOA”).

- e. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.⁴²¹

729. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”⁴²²

730. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to ‘downstream’ registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”⁴²³

731. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

⁴²¹ *Id.* at 2-3.

⁴²² *Id.* at 3-4.

⁴²³ *Id.* at p.5.

732. That the same business practices utilized by Mallinckrodt regarding “charge backs” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Distributor Defendants.

733. Through, *inter alia*, the charge back data, the Marketing Defendants could monitor suspicious orders of opioids.

734. The Marketing Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

735. The Marketing Defendants’ failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

736. The Marketing Defendants have misrepresented their compliance with federal law.

737. The wrongful actions and omissions of the Marketing Defendants that caused the diversion of opioids and which were a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff’s racketeering allegations below.

738. The Marketing Defendants’ actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

A. Defendants’ Unlawful Conduct And Breaches Of Legal Duties Caused The Harm Alleged Herein And Substantial Damages

739. As the Marketing Defendants’ efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid- related substance abuse, hospitalization, and death among the people of the United States. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

740. There is a “parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.”⁴²⁴

741. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁴²⁵

742. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”⁴²⁶

743. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.⁴²⁷

744. As shown above, the opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants’ increased distribution of opioids.

745. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

746. Defendants repeatedly and purposefully breached their duties under federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the

⁴²⁴ See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), DOI: 10.1056/NEJMsa1406143, <http://www.nejm.org/doi/full/10.1056/NEJMsa1406143>.

⁴²⁵ See Volkow & McLellan, *supra* n. 75.

⁴²⁶ See Califf et al., *supra* n. 11.

⁴²⁷ See Press Release, Centers for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *supra* n. 71.

widespread diversion of prescription opioids for nonmedical purposes.

747. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiff.

748. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief.

XIV. CONSPIRACY ALLEGATIONS

A. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

1. Conspiracy among Marketing Defendants

749. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

750. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

751. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination,

and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed “pseudoaddiction”; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

752. The Marketing Defendants knew that none of these propositions is true and that there was no evidence to support them.

753. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

754. What is particularly remarkable about the Marketing Defendants’ effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

755. The Marketing Defendants’ unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network’s distinct corporate members.

756. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants

757. The most unnerving tactic utilized by the Marketing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

758. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

759. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

760. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as

proof of the low addiction risk in connection with taking opioids in connection with taking opioids despite its obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

761. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers, such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy...

By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. Conspiracy Among All Defendants

762. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

763. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated

together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

764. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

765. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants’ agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other’s compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants’ facilities.

766. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA’s attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

767. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

768. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of

opioids.

B. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses

1. Continuing Conduct

769. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

770. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

771. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits.

772. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

773. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through

overprescribing and suspicious sales, all of which fueled the opioid epidemic.

774. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

775. The Supply Chain and Marketing Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These

repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

776. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on jurisdiction, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

777. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community deceived the medical community, consumers, the State, and Plaintiff's Community.

778. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiff could not identify the potential defendants in this litigation, and further held that such information was "critical":

This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal, AmerisourceBergen, McKesson, Wal-Mart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiffs' claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

779. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff, other medical providers and the public. These entities and individuals did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

780. The Plaintiff and others reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

C. Facts Pertaining to Punitive Damages

781. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

782. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

783. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and

regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large scale economic loss to communities and government liabilities across the country.

1. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

784. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions, as described more fully below.

a. FDA warnings to Janssen failed to deter Janssen's misleading promotion of Duragesic

785. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of “homemade” promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain unsubstantiated claims, and lack fair balance.” The March 30, 2000 letter detailed numerous ways in which Janssen’s marketing was misleading.

786. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services (“HHS”) sent Janssen a warning letter concerning Duragesic due to “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower potential for abuse compared to other opioid products.” The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

787. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public

health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been ““examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch”” and noted the possibility “that patients and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

b. Governmental action, including large monetary fines, failed to stop Cephalon from falsely marketing Actiq for off-label uses

788. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

789. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora

790. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment

of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

791. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

792. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

d. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin

793. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay \$19

million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

794. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively to market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

e. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

795. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

796. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

[INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

797. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."⁴²⁸

798. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

⁴²⁸ *Id.*

- f. On September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- h. On December 23, 2016, Cardinal agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

799. McKesson’s deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 McKesson MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.”

800. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

801. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its

facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

802. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

803. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.

* * *

They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.

[INTERVIEWER:] And they had none.

DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?⁴²⁹

804. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more

⁴²⁹ Whitaker, Opioid Crisis Fueled by Drug Industry.

generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

805. In short, McKesson, was “neither rehabilitated nor deterred by the 2008 [agreement],” as a DEA official working on the case noted. Quite the opposite, “their bad acts continued and escalated to a level of egregiousness not seen before.” According to statements of “DEA investigators, agents and supervisors who worked on the McKesson case” reported in the Washington Post, “the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.” “Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.”

806. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or “80s,” as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers’ prescriptions.

807. Yet, Purdue failed to cut off these providers’ opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue’s former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years

of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

808. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

809. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

810. The New York Attorney General similarly found that Endo knew, as early as 2011 that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

811. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have

decreased their sales and their profits.

XV. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS (“RICO”) ACT

A. The False Narrative Enterprise

1. The Common Purpose and Scheme of the False Narrative Enterprise

812. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Marketing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

813. In order to unlawfully increase the demand for opioids, the Marketing Defendants formed an association-in-fact enterprise (the “False Narrative Enterprise”) with the Front Groups and KOLs described above. Through their personal relationships, the members of the False Narrative Enterprise had the opportunity to form and take actions in furtherance of the False Narrative Enterprise’s common purpose. The Marketing Defendants’ substantial financial contribution to the False Narrative Enterprise, and the advancement of opioids- friendly messaging, fueled the U.S. opioids epidemic.⁴³⁰

814. The Marketing Defendants, through the False Narrative Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiff, and made misleading statements and misrepresentations about opioids that downplayed

⁴³⁰ *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, February 12, 2018 <https://www.hsdl.org/?abstract&did=808171> (“*Fueling an Epidemic*”), at 1.

the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named “pseudoaddiction”; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

815. The scheme devised, implemented and conducted by the RICO Defendants was a common course of conduct designed to ensure that the RICO Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Marketing Defendants’ drugs. The Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the False Narrative Enterprise’s scheme, including through the unbranded promotion and marketing network as described above.

816. There was regular communication between the Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the

False Narrative Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

817. At all relevant times, the Front Groups were aware of the Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But for the False Narrative Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

818. At all relevant times, the KOLs were aware of the Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the False Narrative Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the False Narrative Enterprise's scheme and common purpose, and reaped substantial benefits.

819. As public scrutiny and media coverage focused on how opioids ravaged communities in Florida and throughout the United States, the Front Groups and KOLS did not challenge the Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the False Narrative Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

820. The Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the False Narrative Enterprise. As described herein, the False Narrative Enterprise's conduct in furtherance of the common purpose of the False Narrative Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

821. In addition to disseminating misrepresentations about the risks and benefits of opioids, the False Narrative Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the False Narrative Enterprise criticized or undermined the CDC Guidelines which represented "an important step - and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain."

822. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

823. The AAPM criticized the prescribing guidelines in 2016, through its immediate

past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

824. The Marketing Defendants alone could not have accomplished the purpose of the False Narrative Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than the Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the False Narrative Enterprise could not have achieved its common purpose.

825. The impact of the False Narrative Enterprise’s scheme is still in place - i.e., the opioids continue to be prescribed and used for chronic pain, and the epidemic continues to injure Plaintiff, and consume Plaintiff’s resources.

826. As a result, it is clear that the Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the False Narrative Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise’s purpose.

2. The Conduct of the False Narrative Enterprise violated Civil RICO

827. From approximately the late 1990s to the present, each of the Marketing Defendants exerted control over the False Narrative Enterprise and participated in the operation or management of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the

risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;
- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the RICO Marketing Defendants, such as veterans and the elderly, and then funding that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

828. The False Narrative Enterprise had a hierarchical decision-making structure that was headed by the Marketing Defendants and corroborated by the KOLs and Front Groups. The Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States including Florida. The Front Groups and KOLs in the False Narrative Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

829. The Front Groups also conducted and participated in the conduct of the False Narrative Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire

facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;
- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

830. The Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."⁴³¹ "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."⁴³²

831. The KOLs also participated in the conduct of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

- g. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;
- h. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be

⁴³¹ *Fueling an Epidemic* at 1.

⁴³² *Id.* at 2.

safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

- i. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;
- j. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- k. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- l. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the Marketing Defendants.

832. The scheme devised and implemented by the Marketing Defendants and members of the False Narrative Enterprise, amounted to a common course of conduct intended to increase the Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The False Narrative Enterprise Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

833. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS, ACPA. The Front Groups, which appeared to be independent, but were not, transmitted the Marketing Defendants' misrepresentations. The Marketing Defendants and the Front Groups thus worked together to promote the goals of the False Narrative Enterprise.

834. The Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

835. Similarly, as discussed in detail above, the Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The Marketing Defendants and the KOLs thus worked together to promote the goals of the False Narrative Enterprise.

4. Pattern of Racketeering Activity

836. The Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketing activity as described herein.

837. The pattern of racketeering activity used by the Marketing Defendants and the False Narrative Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful False Narrative Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Marketing Defendants' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the Marketing Defendants' misrepresentations.

838. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Plaintiff.

839. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Marketing Defendants and

members of the False Narrative Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

840. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain, to, prescribers, regulators and the public, including Plaintiff, the Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

841. The Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

- a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, such as hospitals transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;
- b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally
- d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing

the opioids marketing scheme;

- f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;
- g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;
- h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

842. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

843. To achieve the common goal and purpose of the False Narrative Enterprise, the Marketing Defendants and members of the False Narrative Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the False Narrative Enterprise.

844. The Marketing Defendants, and each member of the False Narrative Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Defendants'

fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

845. Indeed, for the Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

846. The Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Participants

847. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."⁴³³ Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, the Defendants (except for Insys) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that

⁴³³ <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited, Apr. 21, 2018).

the law intended to restrict.

848. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act (“CSA”). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA’s closed system to conduct their own enterprise for their own unlawful gain.

849. As “registrants” under the CSA, Defendants are duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”⁴³⁴ Critically, these Defendants’ responsibilities do not end with the products they manufacture or distribute -- there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies’ opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

850. If morality and the law did not suffice, competition dictates that the Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior

⁴³⁴ 21 C.F.R. 1301.74(b).

(causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

851. The Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial

return.

852. As described above, at all relevant times, the Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

853. At all relevant times, as described above, the Defendants exerted control over, conducted and/or participated in the False Narrative Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

854. The Defendants disseminated false and misleading statements to state and federal regulators claiming that:

- a. the quotas for prescription opioids should be increased;
- b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

- e. they did not have the capability to identify suspicious orders of controlled substances.

855. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁴³⁵

856. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

857. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants’ applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in

⁴³⁵ See *HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

their mandatory reports and their applications for production quotas.

858. The Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

859. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

860. For the purpose of executing the illegal scheme, the Defendants committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

861. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

- d. RICO Supply Chain Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;
- f. RICO Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Marketing Defendants;
- k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;
- l. Payments to the RICO Supply Chain Defendants' lobbyists through the PCF;
- m. Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from the Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

862. The Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

863. Each of the Defendants identified manufactured, shipped, paid for and received

payment for the drugs identified above, throughout the United States.

864. The Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

865. At the same time, the Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids. The Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

866. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

867. The mail and wire transmissions described herein were made in furtherance of the Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiff that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

868. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

869. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

870. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

871. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

872. As described above, the Defendants were repeatedly warned, fined, and found to

be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the Defendants supports this conclusion that the Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.⁴³⁶

873. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims. The Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

874. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation Of Rico, 18 U.S.C. 1961, et seq. – Opioid False Narrative Enterprise (Against All Defendants)

875. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

⁴³⁶ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

876. This Claim for relief alleges violations of Section 1962(c) and (d) of RICO, 18 U.S.C. §§ 1962(c) & (d)

877. At all relevant times, the Plaintiff was an entity capable of holding a legal or beneficial interest in property, which means that it was a “person” within the meaning of Sections 1961(3) and 1962(c) of RICO, 18 U.S.C. §§ 1961(3) & 1962(c).

I.THE FALSE NARRATIVE ENTERPRISE

878. **Name, Purposes and Membership.** At all relevant times, there existed an “enterprise,” within the meaning of Sections 1961(4) and 1962(c) of RICO, 18 U.S.C. §§ 1961(4) & 1962(c) – to wit, an association-in-fact comprised of each of the Defendants - The False Narrative Enterprise. The lawful purpose of the False Narrative Enterprise was the manufacture, marketing and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the False Narrative Enterprise was to engage in and carry out an intentional scheme to defraud purchasers, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

879. **Continuity:** The continuity of the False Narrative Enterprise was coterminous with the period of time necessary to defraud Plaintiff, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

880. **Effect on Commerce:** The False Narrative Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

881. **Predicate Acts:** At all relevant times, Defendants, in violation of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of racketeering activity, by engaging in multiple, repeated, and continuous violations of the federal wire fraud

statute, 18 U.S.C. § 1343, and the federal mail fraud statute, 18 U.S.C. § 1341, and the Controlled Substances Act, 21 U.S.C. 801, et seq. The Defendants transmitted communications through U.S. mail fraud and interstate wire fraud, in interstate or foreign commerce, to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud Plaintiff, other hospitals, health care providers, patients and their families and, in general, the American public.

882. **Structure of the False Narrative Enterprise:** The False Narrative Enterprise reflected several types of participants, not all of which were complicit, and not all of which are named herein as Defendants:

- (A) **The Marketing Defendants.** The Marketing Defendants are Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt. The Marketing Defendants conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products.
- (B) **The Front Groups.** The Marketing Defendants used the Front Groups, such as the American Pain Foundation, American Academy of Pain Medicine, the American Pain Society, the Federation of State Medical Boards, the Alliance for Patient Access, the U.S. Pain Foundation, the American Geriatrics Society, and the American Chronic Pain Association, not named as defendants herein and not all of which were fully complicit, to stoke demand for opioids by falsely creating the impression of independent third party authoritative validation of the false claims of the Marketing Defendants.

- (C) **The KOLs.** The Marketing Defendants used KOLs, such as Dr. Portenoy, Dr. Webster, Dr. Fine and Dr. Fishman, not named as defendants herein and who may not have been fully complicit, to provide ostensibly valid, third party, authoritative validation of the false claims of the Marketing Defendants.
- (D) **The Distributor Defendants.** The Distributor Defendants are Cardinal, McKesson, and AmerisourceBergen; they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act.
- (E) **Corrupt Physicians and Pharmacies, a/k/a the Pill Mills.** These participants, not named as defendants herein, prescribed opioids illegally and with no basis in legitimate medicine; and dispensed opioids illegally and in direct violation of their legal obligations
- (F) **The National Retail Pharmacies.** The National Retail Pharmacies are CVS, Kroger, ~~Rite Aid~~, Walgreens, and Wal-Mart. Like the Distributor Defendants, they joined the False Narrative Enterprise with full awareness and complicity, and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act.

883. In violation of Section 1962(d) of RICO, 18 U.S.C. § 1962(d), the Defendants, with full knowledge and purpose, conspired to violate Section 1962(c) of RICO.

II.CONSEQUENCES

884. By reason of the above-referenced violations of Section 1962(c) and (d) of RICO, 18 U.S.C. § 1962(c) & (d), Plaintiff was injured in its business or property within 18 U.S. § 1964(c) of RICO, is entitled to assert this claim, and to recover threefold the damages they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief, as the Court may provide.

SECOND CLAIM FOR RELIEF

Violation OF RICO (A violation of 18 U.S.C. § 1962 (d) and (a)) (Against Each of the Defendants)

885. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

886. This claim for relief alleges a violation of Section 1962 (d) and (a) of RICO, 18 U.S.C. § 1962 (a) & (d). It is asserted against each of the Defendants.

887. At all relevant times, Plaintiff and each Defendant in this Count was an "entity" capable of holding a legal or beneficial interest in property, which means that each of them is a "person" within the meaning of Sections 1961(3) and 1962(d) of RICO, 18 U.S.C. §§ 1961(3), 1962(d).

888. Each Defendant, as a "legal entity," was an "enterprise" within the meaning of Sections 1961(4) and 1962 (a) of RICO, 18 U.S.C. § §1961(4), 1962 (a) (d).

889. Each Defendant engaged in interstate or foreign commerce,

890. Each Defendant transmitted by U.S. mail and interstate wire communications, in interstate or foreign commerce, communications or other matter to designated persons for

ostensibly legitimate purposes, but with the actual, unlawful purpose of facilitating an intentional scheme to defraud Plaintiff and other victims of vast sums of money.

891. Each of the Defendants engaged in a pattern of racketeering activity by engaging in multiple, repeated, and continuous violations of the federal mail fraud statute, 18 U.S.C. § 1341, the federal wire fraud statute, 18 U.S.C. § 1343, and the Controlled Substances Act, 21 U.S.C. § 801 et seq.

892. In violation of Section 1962(a) of RICO, 18 U.S.C. § 1962(a), and through the above-referenced pattern of racketeering activity, Defendants, having income derived, directly or indirectly, from a pattern of racketeering, in which it participated as a principal within the meaning of 18 U.S.C. § 2, used or invested, directly or indirectly, part of such income in itself, an enterprise.

893. In violation of Section 1962(d) of RICO, 18 U.S.C. § 1962(d), Defendants, with full knowledge and purpose, conspired to violate Section 1962 (a) of RICO.

I. CONSEQUENCES

894. By reason of the above-referenced violations of Section 1962 (d) and (a) of RICO, 18 U.S.C. §§ 1962 (a) & (d), Plaintiff was injured in its business or property, within the meaning of 18 U.S.C. § 1964(c), 18 U.S.C. § 1964(c), through the above-referenced acts of racketeering, is entitled to assert this claim, to recover threefold the damages it sustained, as determined at trial, and the cost of the suit, including reasonable attorneys' fees, and such other appropriate relief, as the Court may determine.

THIRD CLAIM FOR RELIEF

Violation Of Florida's Deceptive And Unfair Trade Practices Act (Fla. Stat. Ann. § 501.201, et seq.) (Against All Defendants)

895. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth

in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

896. This cause of action is brought pursuant to sections 501.201 to 501.213, Florida Statutes, which is known as the Florida Deceptive and Unfair Trade Practices Act (FDUTPA).

897. FDUTPA “shall be construed liberally to promote the following policies: (1) To simplify, clarify, and modernize the law governing consumer protection, unfair methods of competition, and unconscionable, deceptive, and unfair trade practices; (2) To protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce; [and] (3) To make state consumer protection and enforcement consistent with established policies of federal law relating to consumer protection.” Fla. Stat. § 501.202(2).

898. Section 501.204(1), Florida Statutes declares as unlawful “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Fla. Stat. § 501.204(1).

899. Plaintiff is a “person” within the meaning of Fla. Stat. § 501.203(6) and as envisioned in Fla. Stat. § 501.211.

900. All Defendants engaged in “[t]rade or commerce” within the meaning of Fla. Stat. § 501.203(8).

901. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the FDUTPA by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids’ safety and efficacy, and downplaying or omitting the risk of addiction arising from

their use.

902. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of “registrants” by the federal CSA, 21 C.F.R. § 1301.74(b), which is incorporated into Florida law by the FL DCA, including Fla. Stat. 499.0121. The CSA defines “registrant” as any person who is registered pursuant to 21 U.S.C § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

903. Defendants’ unfair or deceptive acts or practices in violation of the FDUTPA offend Florida’s public policy, are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will, and they caused substantial injury to Plaintiff. Plaintiff risks irreparable injury as a result of the Marketing Defendants’, Distributor Defendants’, and the National Retail Pharmacy Defendants and their agents’ acts, misrepresentations and omissions in violation of the FDUTPA, and these violations present a continuing risk to Plaintiff, as well as to the general public.

904. As a direct and proximate result of Defendants’ violations of the FDUTPA, Plaintiff has suffered and continues to suffer injury-in-fact and actual damages.

905. Defendants violated the FDUTPA because they engaged in false or misleading statements about the efficacy and safety of opioid pharmaceuticals.

906. Defendants, individually and acting through acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiff to induce it to purchase, administer, and consume opioids as set

forth in detail above.

907. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

908. Defendants intended that Plaintiff, physicians, patients, and/or others would rely on their misrepresentations and omissions.

909. Plaintiff, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

910. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

911. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff, physicians, patients, and/or others suffered actual pecuniary damage.

912. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

913. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF

Fraudulent Practices – Misleading Advertising, Florida Statutes Title XLVI, Crimes § 817.41 (Against Marketing Defendants)

914. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

915. Pursuant to Florida Statute, Title XLVI, Crimes, § 817.41(1):

it shall be unlawful for any person to make or disseminate or cause to be made or disseminated before the general public of the state, or any portion thereof, any misleading advertisement. Such making or dissemination of misleading advertising

shall constitute and is hereby declared to be fraudulent and unlawful, designed and intended for obtaining money or property under false pretenses.

916. “Misleading advertising is defined by § 817.40(5) as:

...any statements made, or in oral, written, or printed form or otherwise, to or before the public, or any portion thereof, which are known, or thorough the exercise of reasonable care or investigation could or might have been ascertained, to be untrue or misleading, and which are or were so made or disseminated with the intent or purpose, either directly or indirectly, or selling or disposing of real or personal property, services of any nature whatever, professional or otherwise, or to induce the public to enter into any obligation relating to such property or services.

917. Defendants engaged in misleading advertising in the conduct of a business, trade or commerce in this state.

918. Defendants engaged in false or misleading advertising in deceiving the public about the efficacy and safety of opioid pharmaceuticals.

919. The ways in which Defendants’ advertising was misleading include but are not limited to:

- a. Misrepresenting the truth about how opioids lead to addiction;
- b. Misrepresenting that opioids improve function;
- c. Misrepresenting that addiction risk can be managed;
- d. Misleading doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- e. Falsely claiming that withdrawal is simply managed;
- f. Misrepresenting that increased doses pose no significant additional risks;
- g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

920. Plaintiff has been injured by reason of Defendants’ violation.

921. Pursuant to Florida Statute, Title XLVI, Crimes, § 817.41(6), plaintiff is entitled

to costs, attorney's fees, and punitive damages, in addition to actual damages proven.

FIFTH CLAIM FOR RELIEF

**Breach of Implied Warranty of Fitness For a Particular Purpose
(Fla. Stat. Ann. §§ 672.315 and 672.11, et seq.)
(Against All Defendants)**

922. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

923. Plaintiff purchased opioid products from Defendants that were not suitable for Plaintiff's use to appropriately treat Plaintiff's patients.

924. At the time of Plaintiff's purchases, Defendants knew or had reason to know that Plaintiff intended to use the opioids for a particular purpose, namely to provide pain relief in an appropriate way that did not unnecessarily endanger its patients if the opioids were used as sold and marketed by Defendants.

925. At the time of Plaintiff's purchases, Defendants knew or had reason to know that Plaintiff was purchasing the opioids for the particular purposes described above and was relying on Defendants' skill, judgment and narrative to provide opioids that were suitable.

926. Plaintiff justifiably relied on Defendants.

927. The opioids that Plaintiff purchased were not suitable for the particular purpose for which Plaintiff purchased them.

928. As a result, Plaintiff has been damaged in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF

**Negligence
(Against All Defendants)**

929. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

930. To establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and loss or damage caused by the breach, and actual loss or damage to another. All such essential elements exist here.

931. Each Defendant had a duty to exercise reasonable care in the manufacturing, marketing, selling, and distributing of highly dangerous opioid drugs.

932. Each Defendant breached its aforesaid duties by its conduct previously specified herein.

933. As a proximate result, Defendants have caused Plaintiff's injury related to the treatment of opioid-related conditions. Plaintiff has incurred massive costs by providing uncompensated care as a result of opioid related conditions.

934. Each Defendant owed its aforesaid duties to Plaintiff because the injuries alleged herein were foreseeable by the Defendants.

935. The injuries to Plaintiff would not have happened in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture, marketing, sale and distribution of opioids.

936. Plaintiff seeks compensatory damages for its monetary losses previously specified herein, plus interest and the costs of this action.

SEVENTH CLAIM FOR RELIEF

Wanton Negligence (Against All Defendants)

937. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

938. Defendants conducted themselves with reckless indifference to the consequences of their acts and omissions, in that they were conscious of their conduct and were

aware, from their knowledge of existing circumstances and conditions, that their conduct would inevitably or probably result in injury to others, specifically hospitals such as Plaintiff, which would be subjected to providing unreimbursed healthcare treatment to patients with opioid conditions.

939. As a proximate result of Defendants' wanton negligence, Plaintiff was monetarily damaged as aforesaid.

940. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

EIGHTH CLAIM FOR RELIEF

Negligence Per Se (Against All Defendants)

941. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

942. Defendants violated requirements of the Controlled Substance Act, 21 U.S.C. § 801, et seq., by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from documents filed with the DEA.

943. Defendants have a duty to comply with the regulations of the Florida Drug and Cosmetic Act. (FDCA), Florida Statutes, Title XXXIII, Chapter 499, et seq. and the Controlled Substances Act.

944. Failure to comply with the FDCA and CSA constitutes negligence per se.

945. Defendants failed to comply with the FDCA and CSA.

946. In the instant case, as detailed above, the FDCA and CSA require that the Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to

ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

947. Defendants have failed to diligently respond to the suspicious orders which Defendants have filled.

948. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Florida and federal law.

949. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

950. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances and thereby creating and continuing addictions to prescription medications in this state.

951. Defendants have by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiff by violating Florida and federal law, by creating conditions which contribute to the violations of Florida and federal laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

952. Plaintiff has suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Florida and federal law.

953. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

954. Defendants are in a class of a limited number of parties that can legally sell and distribute opioids, which places it in a position of great trust.

955. The trust placed in Defendants by Plaintiff through the license to distribute opioids creates a duty on behalf of Defendants to prevent diversion of the medications it supplies to illegal purposes.

956. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the Plaintiff from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

957. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

958. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

959. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

960. Defendants are in exclusive control of the management of the opioids it has distributed.

961. Plaintiff is without fault, and the injuries to the Plaintiff and its patients would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

962. Plaintiff is within the class of persons the FDCA and the CSA was intended to protect.

963. The harm that has occurred is the type of harm that the FDCA and the CSA was intended to guard against.

964. Defendants breached their duty by failing to take any action to prevent or reduce the distribution of the opioids.

965. As a direct and proximate result of Defendants' negligence per se, the Plaintiff has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids.

966. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

967. Defendants were negligent in failing to monitor against diversion of opioid pain medications.

968. Defendants' violations constitute negligence per se.

969. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

NINTH CLAIM FOR RELIEF

Negligent Marketing (Against Marketing Defendants)

970. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein

971. Defendants had a duty to exercise reasonable care in the marketing of opioids.

972. Defendants were aware of the potentially dangerous situation involving opioids.

973. Defendants marketed opioids in an improper manner by:

- a. Overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
- b. Trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose and death;
- c. Overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
- d. Mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;
- e. Marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

974. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

975. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

976. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b)

a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

977. Defendants knew or should have known that opioids were unreasonably dangerous and could cause addiction.

978. Defendants have a duty to exercise reasonable care in the distribution, promotion and marketing of opioids.

979. Defendants breached their duty by failing to take any action to prevent or reduce the unlawful distribution of opioids.

980. Defendants' marketing was a factor for physicians, patients, and others to prescribe or purchase opioids.

981. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and care of addiction or risk of addiction to opioids.

982. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

TENTH CLAIM FOR RELIEF

Negligent Distribution (Against All Defendants)

983. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein

984. Defendants had a duty not to breach the standard of care established under Florida law and the Controlled Substance Act (“CSA”) and implementing regulations and to exercise reasonable care in the distribution of opioids.

985. Defendants were aware of the potentially dangerous situation involving opioids.

986. Defendants distributed opioids in an improper manner by:

- a. Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;
- b. Distributing and selling opioids without maintaining effective controls against diversion;
- c. Choosing not to or failing to effectively monitor for suspicious orders;
- d. Choosing not to or failing to report suspicious orders;
- e. Choosing not to or failing to stop or suspend shipments of suspicious orders; and
- f. Distributing and selling opioids prescribed by “pill mills” when Defendants knew or should have known the opioids were being prescribed by “pill mills.”

987. Defendants’ negligent breach of their duties resulted in foreseeable harm and injury to Plaintiff.

988. As a direct and proximate result of Defendants’ negligence, Plaintiff suffered and will continue to suffer damages including costs related to uncompensated care and other costs related to the distribution of opioids which never should have been sold.

989. Plaintiff is entitled to recover damages caused by Defendants’ negligence in an amount to be determined at trial.

ELEVENTH CLAIM FOR RELIEF

Nuisance (Against All Defendants)

990. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth

in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

991. The nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic area served by Plaintiff for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

992. All Defendants substantially participated in nuisance-causing activities.

993. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiff, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

994. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

995. Defendants' activities unreasonably interfere with the economic rights of Plaintiff.

996. The Defendants' interference with these rights of Plaintiff is unreasonable because it:

- a. Has harmed and will continue to harm the public health services of and public peace of Plaintiff;
- b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiff serves;
- c. Is proscribed by statutes and regulation, including the CSA, pharmacy regulations, and the consumer protection statute;
- d. Is of a continuing nature and it has produced long-lasting effects;
- e. Defendants have reason to know their conduct has a significant effect upon

Plaintiff; and

f. Has inflicted substantial costs on Plaintiff.

997. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

998. The resources of Plaintiff are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

999. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

1000. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiff and in the geographic area served by Plaintiff.

1001. As a direct and proximate result of the nuisance, Plaintiff has sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, the Defendants created a mess, leaving it to the Plaintiff and other hospitals the costs of cleaning it up. This is a classic nuisance.

1002. As a result of Defendants' actions, Plaintiff has suffered a special injury, different from that suffered by the public at large by individual users and by governmental

entities, namely that Plaintiff has provided uncompensated care for patients suffering from opioid related conditions.

1003. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

1004. Defendants should be required to pay the expenses Plaintiff has incurred or will incur in the future to fully abate the nuisance.

TWELFTH CLAIM FOR RELIEF

Unjust Enrichment (Against All Defendants)

1005. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

1006. Plaintiff provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating. Plaintiff thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

1007. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, hospitals throughout the United States to provide unreimbursed healthcare treatment to patients with opioid conditions that Defendants were responsible for creating.

1008. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

1009. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

1010. Defendants have therefore been unjustly enriched.

1011. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff asks that the Court:

- A. Enter judgment against Defendants, jointly and severely, and in favor of Plaintiff;
- B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages; treble damages; punitive damages; pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate, including disgorgement of illicit proceeds and other orders as provide in 18 U.S.C. § 1964;
- C. Award Plaintiff their cost of suit, including reasonable attorneys' fees as provided by law; and
- D. Award such further and additional relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: May 3, 2018

Respectfully Submitted,

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